IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: GENERIC DIGOXIN AND DOXYCYCLINE ANTITRUST LITIGATION	**MDL NO. 2724** **16-MD-2724** **HON. CYNTHIA M. RUFE**
THIS DOCUMENT RELATES TO: **ALL ACTIONS**	

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT LANNETT COMPANY, INC.'S MOTION TO DISMISS CONSOLIDATED AMENDED CLASS ACTION COMPLAINTS OF DIRECT PURCHASER PLAINTIFFS AND END-PAYER PLAINTIFFS

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Defendant Lannett Company, Inc. ("Lannett") respectfully submits this memorandum of law in support of its motion to dismiss the Direct Purchaser Plaintiffs' Consolidated Amended Class Action Complaint ("DPP Complaint") and the End-Payer Plaintiffs' Corrected Consolidated Complaint ("EPP Complaint") (collectively, the "Complaints"). Lannett joins in and incorporates by reference Certain Defendants' Memorandum of Law in Support of Joint Motion to Dismiss Direct Purchaser Plaintiffs' Consolidated Amended Class Action Complaint and Certain Defendants' Joint Memorandum of Law in Support of Their Motion to Dismiss the End-Payer Plaintiffs' Corrected Consolidated Class Action Complaint (collectively, the "Joint Briefs"). Lannett submits this supplemental memorandum to address Plaintiffs' theory that Lannett's public quarterly earnings calls somehow support the claim that Lannett conspired to fix the price of generic digoxin and generic doxycycline hyclate. Although Plaintiffs' allegations regarding Lannett's quarterly earnings calls may add volume to the Complaints, they add no substance as required under *Twombly*.

INTRODUCTION

To characterize Plaintiffs' allegations regarding Lannett as thin would be more than generous. Although Plaintiffs claim that Lannett conspired to fix the price of digoxin and doxycycline hyclate, they do not—and cannot—allege that Lannett sold doxycycline hyclate during the alleged conspiracy period (it did not). Moreover, Plaintiffs allege no facts demonstrating that Lannett communicated with competitors about digoxin pricing, or regarding how or when Lannett supposedly participated in the formation of any alleged conspiracy to fix the price of digoxin.

Instead, Plaintiffs base their claims against Lannett entirely on circumstantial allegations that (1) Lannett increased the price of generic digoxin one time, following the branded

manufacturer's decision to increase price; (2) Impax, the only generic competitor at the time, followed Lannett's price increase; (3) unidentified Lannett employees attended certain trade association meetings (but there are no allegations they discussed digoxin pricing while there); (4) the Department of Justice is investigating the generic drug industry generally; and (5) Lannett executives made certain public statements during earnings calls. That is it. *Twombly*, however, requires much more. *See* DPP MTD at pp. 8-9; EPP MTD at pp. 4, 7-9.

Lannett submits this supplemental memorandum to focus on a particular aspect of Plaintiffs' allegations—specifically, those related to Lannett's earnings calls. Plaintiffs rely heavily on those earnings calls in an effort to plug the gaping hole left by their inability to plead basic facts demonstrating how, when or by whom the alleged conspiracy was formed. The earnings calls, however, do nothing to bolster Plaintiffs' allegations.

In the Complaints, Plaintiffs selectively quote portions of five *public* earnings calls Lannett executives held with investors and analysts. *See* DPP Compl. ¶¶ 123-32; EPP Compl. ¶¶ 111-17. These quarterly earnings calls occurred between September 10, 2013 and February 4, 2015. There is, of course, nothing remarkable about holding earnings calls. Lannett is a publicly-traded company, and the purpose of these calls is to educate the public, including investors and analysts, on events affecting the performance of the company and potential strategies going forward.[1]

[1] The entire transcripts of the five earnings calls Plaintiffs quote from are publicly available. For the Court's convenience, they are attached hereto as Exhibits 1-5. "[A]lthough a district court may not consider matters extraneous to the pleadings, a document integral to or explicitly relied upon in the complaint may be considered without converting the motion to dismiss into one for summary judgment." *U.S. Express Lines, LTD. v. Higgins*, 281 F.3d 383, 388 (3d Cir. 2002) (internal quotation marks and citation omitted); *see also Hynoski v. Columbia Cty. Redevelop. Auth.*, 941 F. Supp. 2d 547, 555 (M.D. Pa. 2013) ("The court may . . . take judicial notice of certain facts, as well as undisputedly authentic documents if the complainant's claims are based upon these documents."). Because the Complaints specifically rely on and quote directly from these earnings calls, the Court may properly consider the full contents of these transcripts on this motion to dismiss.

Further, there was nothing unusual about the content of the earnings calls, led by Lannett CEO Arthur Bedrosian and/or CFO Martin Galvin. None of Bedrosian's or Galvin's statements during these calls can reasonably be construed as contributing to the formation of an alleged conspiracy to fix the price of digoxin. Neither the timing nor the content of the calls fits with the claimed conspiracy.

As Plaintiffs allege, Lannett raised digoxin prices only once during the class period, in October 2013. *See* DPP Compl. ¶ 81; EPP Compl. ¶ 80. They cite only a single earnings call, on September 10, 2013, that preceded that price increase. But Plaintiffs identify nothing from that call disclosing, explicitly or implicitly, that Lannett either intended to increase prices for digoxin or invited others to do so. The statements from the September 10, 2013 call are either general industry commentary in response to questions from analysts or do not relate to digoxin. The statements made during this earnings call also demonstrate uncertainty regarding competitors' pricing, which wholly undermines Plaintiffs' theory.

Moreover, Impax was the only other manufacturer of digoxin at the time of the 2013 price increase. DPP Compl. ¶ 79. Plaintiffs do not allege that anyone at Impax participated in, listened to, or read a transcript of that call. Nor do Plaintiffs allege that Impax responded in any way *before* Lannett implemented its price increase in mid-October 2013. The only public statements by Impax cited in the Complaints came *after* Lannett's price increase and merely stated that Impax also increased prices. That series of events hardly suggests that the companies used earnings calls to form a conspiracy or provide assurances regarding intended price increases. Indeed, viewed in their entirety, the earnings calls show that Lannett's pricing was entirely consistent with non-collusive, independent behavior.

The other public statements Plaintiffs rely upon occurred *after* Lannett's only digoxin price increase and are, therefore, wholly irrelevant to the formation of an alleged conspiracy to fix the price of digoxin. In addition, many of the excerpts cited by Plaintiffs are cherry-picked and presented out of context. When read in context, many of these excerpts specifically refer to other drugs or demonstrate that, contrary to the claimed conspiracy, Lannett executives actually were uncertain about competitors' pricing and the sustainability of price increases. In addition, the November 7, 2013 earnings call in particular provides a legitimate, non-conspiratorial explanation for Lannett's decision to increase prices in October 2013. *See infra* at pp. 13-14.

Plaintiffs, therefore, do not plausibly plead that Lannett conspired to fix the price of digoxin.

ARGUMENT

To survive a motion to dismiss, a complaint must "plead enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *see Ashcroft v. Iqbal*, 556 U.S. 662, 678-79 (2009). "Where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has . . . not show[n] . . . that the pleader is entitled to relief." *Fowler v. UPMC Shadyside*, 578 F.3d 203, 211 (3d Cir. 2009) (internal quotation marks omitted). Allegations that "merely create[] a suspicion" of an antitrust violation fall short of this plausibility standard. *Twombly*, 550 U.S. at 555. Instead, allegations must go beyond implying a possibility of wrongdoing and *suggest* a violation occurred. *Id.*

The Complaints fall far short of the mark established by *Twombly*. *See* DPP MTD at pp. 8-9; EPP MTD at pp. 4, 7-9. Among their other failings, the Complaints allege no facts, direct or circumstantial, demonstrating how the claimed conspiracy was formed, when it was formed or by whom it was formed. Absent such elemental facts, the remaining allegations of the Complaints,

such as those related to alleged parallel pricing or attendance at trade association events, assume the existence of a conspiracy and characterize innocuous events as "proof" of that assumed conspiracy. Such pleading is insufficient to establish a claim for a Section 1 conspiracy. *See Blomkest Fertilizer, Inc. v. Potash Corp. of Saskatchewan*, 203 F.3d 1028, 1037 (8th Cir. 2000) ("[T]he class may not proceed by first assuming a conspiracy and then setting out to prove it."). Indeed, relying on innocuous events as proof of an assumed conspiracy is particularly inappropriate where, as here, the facts suggest an "obvious alternative explanation" for those events other than a conspiracy. *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 322 (3d Cir. 2010) (quoting *Twombly*, 550 U.S. at 567).

Plaintiffs attempt to plug this hole in their Complaints by relying on the Lannett earnings calls. Those calls, however, cannot reasonably be construed as contributing to the formation of the claimed conspiracy.

I. ANALYST CALLS MUST HAVE THE RIGHT TIMING, CONTENT, AND LACK A PUBLIC PURPOSE TO PLAUSIBLY SUPPORT AN INFERENCE OF CONSPIRACY

While courts have sometimes relied (in part) on allegations regarding defendants' public statements relating to pricing, capacity reduction or other competitive conduct in holding that claims of conspiracy satisfied *Twombly*, those public statements possessed certain specific characteristics, none of which is present here.

First, in those cases, the pattern of statements reflected a back-and-forth dialogue leading to an agreed-upon position, or at least an exchange of assurances, before the action that was the alleged subject matter of the conspiracy. *Compare In re Delta/AirTran Baggage Fee Antitrust Litig.*, 733 F. Supp. 2d 1348, 1361-62 (N.D. Ga. 2010) (allegations described "six-month dialogue [using public statements] between the parties concerning each Defendant's own plans to reduce capacity, increase prices, and set expectations as to what the other needed to do to increase prices")

with Credit Bureau Servs., Inc. v. Experian Info. Sols., Inc., 2012 WL 6102068, at *17 (S.D. Fla. Dec. 7, 2012) (complaint "lack[ed] any averments demonstrating the mutuality of Experian's alleged response to First American's" public statements).

Second, the statements contained a level of specificity regarding the defendants' intended conduct, often initiated by an invitation for action across the industry. *See, e.g.*, *In re Domestic Airline Travel Antitrust Litig.*, 2016 WL 6426366, at *8-9 (D.D.C. Oct. 28, 2016) (complaint identified numerous detailed public statements regarding defendants' plans to alter capacity); *In re Delta/Air Tran*, 733 F. Supp. 2d at 1361 (public statements specified "plans to reduce capacity, increase prices, and set expectations as to what the other [company] needed to do to increase prices"). Absent such specificity, general statements regarding industry conditions cannot support claims of conspiracy. *See In re Plasma-Derivative Protein Therapies Antitrust Litig.*, 764 F. Supp. 2d 991, 1001 (N.D. Ill. 2011) ("It is difficult to imagine how generic statements [regarding industry trajectory] render the conspiracy allegation more plausible.").

Third, the statements reflected an absence of public purpose justifying them. *See Standard Iron Works v. ArcelorMittal*, 639 F. Supp. 2d 877, 887 (N.D. Ill. 2009) ("Defendants have candidly admitted that the reason for their production cuts was to decrease supply to keep prices high."); *In re Petroleum Prods. Antitrust Litig.*, 906 F.2d 432, 445-48 (9th Cir. 1990) (same); *see also Grasso Enters., LLC v. Express Scripts, Inc.*, 2017 WL 365434, at *5 (E.D. Miss., Jan. 25, 2017) (publicly broadcasting "sensitive business information, plans or strategies" as opposed to general statements about publicly known facts was contrary to company's self-interest and lacked proper purpose).

By contrast, where such hallmarks are absent, courts have held that public statements related to pricing or other competitive conduct do nothing to support a claim of conspiracy. *See, e.g.*, *Credit Bureau*, 2012 WL 6102068, at *16-17 (granting defendants' motion to dismiss). In

Credit Bureau, plaintiffs alleged that defendants used public statements to further an antitrust conspiracy, and argued that such allegations were sufficient to survive a motion to dismiss under *In re Delta/Air Tran*. *Id.* The court rejected plaintiff's argument because it failed to allege facts showing a back-and-forth pattern of public statements leading to an agreed-upon position. *Id.* at *17. The court distinguished *In re Delta/Air Tran*, observing that, in that case, "both AirTran and Delta *each* indicated what the agreed-upon position was *before* either party engaged in the agreed-upon activity." *Id.* at *17 (emphasis added); *see also Valspar Corp. v. E.I. du Pont de Nemours*, 152 F. Supp. 3d 234, 247-48 (D. Del. 2016) (publicly issued advance price announcements followed by actual pricing changes, without more, were not suggestive of conspiracy in oligopolistic market); *Holiday Wholesale Grocery Co. v. Philip Morris Inc.*, 231 F. Supp. 2d, 1253, 1276 (N.D. Ga. 2002) ("the cases which have found that an inference of traditional agreement from indirect communications took place show far more detailed communications with no public purpose"), *aff'd sub nom Williamson Oil Co., Inc. v. Philip Morris USA*, 346 F.3d 1287 (11th Cir. 2003).

Here, it is apparent from the face of the Complaints that none of the Lannett analyst calls upon which the Plaintiffs rely possesses any of the characteristics suggesting that they could have contributed to the formation of a conspiracy. To the contrary, the calls show uncertainty about competitors' behavior and demonstrate there was no dialogue before Lannett's price increase in October 2013.

A. The Alleged Public Statements by Lannett Executives Add Nothing to Plaintiffs' Allegations of Conspiracy

Twombly and its progeny require that the allegations of the Complaints must be viewed in context. *See Twombly*, 550 U.S. at 557, 568 n.13. When placed in context, and stripped of

Plaintiffs' conclusory characterizations, the timing and the content of Lannett's earnings calls simply do not support an inference of a conspiracy to fix the price of digoxin.[2]

B. The September 10, 2013 Public Call Is the Only Communication That Preceded the Lannett Price Increase

As Plaintiffs allege, Lannett increased its price of digoxin only once during the class period, in October 2013. *See* DPP Compl. ¶¶ 81-82, 134; EPP Compl. ¶ 80. Plaintiffs point to only one analyst call, on September 10, 2013, that preceded Lannett's October 2013 price increase. *See* DPP Compl. ¶¶ 123-24; EPP Compl. ¶ 111. Although Plaintiffs characterize the September 10 earnings call as an "invitation" to Impax to increase digoxin prices, *see* DPP Compl. ¶ 135, it revealed no information regarding Lannett's intentions with respect to digoxin prices. The portion of the September 10, 2013 earnings call that Plaintiffs rely upon (with the analyst's question added) is as follows:

> Rohit Vanjani—Oppenheimer & Co. Inc.—So on the gross margin, is that just more of the same, it's manufacturing efficiencies, product launches, sales mix and then pricing? I mean, I kind of thought of you guys as a price follower or maybe you can kind of you go out and you take price sometimes and see if it works, but I wouldn't think that'd be embedded in guidance?
>
> Arthur Bedrosian, CEO, Lannett—Well, I may take steps. We're not a price follower. We tend to be a price leader on price increasing and the credit goes to my sales vice president. He takes an aggressive stance towards raising prices. He understands one of his goals, his objectives as a sales vice president is to increase profit margins for the company. And he's the first step in that process. I can reduce costs and manufacturing efficiencies, but it has to be combined with sales increase, a profit increase, as I should say, by the salespeople. And he's done a good job there. With 1 or 2 exceptions, we've tended to lead in the way of price increases. We believe that these prices are important. We need to try raising them. Sometimes, it doesn't stick and we have to go back and reduce our price, and other times it does. I am finding a climate out there has changed dramatically and I see more price increases coming from our competing - - competitors than I've seen in the past. And we're going to continue to lead. We have more price increases planned for this year within our budget. And hopefully, our competitors follow suit. If they don't, that's their issue. But our plan is to raise prices on any product that we think we can or we haven't raised a price.

[2] Since it is undisputed that Lannett did not manufacture or sell doxycycline hyclate, it obviously could not conspire to fix the price of that drug.

September 10, 2013 Lannett Analyst Call Transcript at p. 15, attached hereto as Exhibit 1; DPP Compl. ¶ 123. The EPP Complaint actually omits the question and about half of Mr. Bedrosian's response, including the critical reference to the occasional failure of price increases to "stick" and the need to later reduce prices. *See* EPP Compl. ¶ 111.

The September 10 statement lacks any of the hallmarks suggesting it contributed to the formation of a conspiracy. First, this statement was not part of a back-and-forth dialogue leading to an agreed-upon position, or exchange of assurances, among various Defendants, because there was no dialogue at all. *See Credit Bureau*, 2012 WL 6102068 at *17. At the time, Impax was the only other seller of digoxin. *See* DPP Compl. ¶ 79. Plaintiffs do not allege that Impax participated in, listened to, or read a transcript of that call. Nor do they allege that Impax ever responded to the statements in the call before Lannett announced its digoxin price increase. To the contrary, Plaintiffs allege that Lannett increased its digoxin price prior to any statement or action by Impax. DPP Compl. ¶¶ 81, 134; EPP Compl. ¶¶ 80, 118. Lannett had no assurance that its only generic competitor at the time would follow its price increase. If anything, the timing demonstrates "unilateral" behavior, not an agreement to fix prices. *Credit Bureau*, 2012 WL 6102068, at *17.

Second, Mr. Bedrosian's response to an analyst's question lacks the specificity of other public statements that courts have found might support claims of conspiracy. In contrast to cases like *In re Delta/Air Tran*, Mr. Bedrosian's statement reveals nothing about Lannett's business operations or plans to increase pricing in a specific context. *See* 733 F. Supp. 2d at 1362. It makes no reference to digoxin prices in particular, but rather explains Mr. Bedrosian's approach to drug pricing in general and his perspective that Lannett is a "price leader." Further, the September 10 statement was made "in response to analysts' questions rather than from prepared speeches and statements," thus undercutting its "probative value." *Id.* The statement amounted to nothing more

than the "type of information companies legitimately convey to their shareholders." *Holiday Wholesale Grocery*, 231 F. Supp. 2d at 1277.

Third, if anything, Mr. Bedrosian's statement during the September 10, 2013 earnings call demonstrates Lannett's uncertainty regarding competitors' potential reactions to price increases. In speaking about price increases in general, without reference to any specific product, competitors, or markets, Mr. Bedrosian noted that "[s]ometimes, [a price increase] doesn't stick and we have to go back and reduce our price, and other times it does." DPP Compl. ¶ 123. He also recognized that competitors might not "follow suit," explaining that "if they don't, that's their issue." *Id.* In fact, Mr. Bedrosian repeated this theme of not knowing what competitors will do or how they determine pricing when questioned about Par's possible entry into the digoxin market in the February 6, 2014 call referred to in the DPP Complaint at ¶¶ 129, 132 and the EPP Complaint at ¶ 113:

> Rohit Vanjani – Okay. So you think it's in line with yours and they've followed suit in terms of that price increase?
>
> Arthur – It's hard to say what's in line. It's not doing us any harm, but I don't know how you describe what's in line. ***I don't talk to them, so I don't really know how they determine their pricing.*** But remember, they're distributing a product as well and they certainly don't want to harm the brand market for which they are offering the authorized generic. So I believe that restrains them. And that's not hurting us. The prices that they're quoting are not doing us any harm at all.

February 6, 2014 Lannett Analyst Call Transcript at pp. 10-11, attached hereto as Exhibit 3 (emphasis added).

Fourth, the September 10 statement also has a proper public purpose in that it is an example of "typical industry reporting on strategy" during a normal and routine earnings call. *Holiday Wholesale Grocery Co.*, 231 F. Supp. 2d at 1275; *see also Standard Iron Works*, 639 F. Supp. 2d

at 896. The statement did not reveal "sensitive business information" or provide a concrete indication of Lannett's future plans. *See Grasso Enters.*, 2017 WL 365434, at *5.

While Plaintiffs cite a few additional statements from the September 10, 2013 earnings call, these are irrelevant because they were actually made about a different product, levothyroxine, in response to analysts' questions about that product. *See* DPP Compl. ¶¶ 124-25. Plaintiffs' efforts to cherry-pick quotes, remove references to levothyroxine, and present statements out of context cannot support their claim of a conspiracy to fix digoxin prices. *See Holiday Wholesale Grocery*, 231 F. Supp. 2d at 1275 (recognizing lack of probative value in public "statements taken out of context").

C. Additional Earnings Call Statements

The Plaintiffs also selectively quote four other Lannett earnings calls. *See* DPP Compl. ¶¶ 126-32; EPP Compl. ¶¶ 111-17. These calls likewise add nothing to Plaintiffs' claim.

First, all four of the calls took place *after* Lannett's sole digoxin price increase in October 2013. *See Standard Iron Works*, 639 F. Supp. 2d at 895 (public statements contributed to conspiracy because they were "***followed by*** the adoption of the proposed behavior") (emphasis added). Second, as with the September 10, 2013 earnings call, the Complaints do not allege that any digoxin competitor ever participated in, listened to, or even accessed a transcript of any Lannett earnings calls or presentations. Therefore, the statements cannot be part of any dialogue between the companies. *See Credit Bureau*, 2012 WL 6102068, at *17.

Third, the most that can be said for these analyst calls is that they serve as vehicles for Plaintiffs' mischaracterization of the words used on the calls for purposes of their Complaints, not the facts themselves. *See, e.g.*, DPP Compl. ¶ 126 ("In a subsequent earnings call, Bedrosian reported that Lannett's chief competitor had indeed heeded its price increase signal."); ¶ 135 (Impax CEO "demonstrated Impax's continued acceptance of Lannett's invitation to increase

prices"); EPP Compl. ¶ 112 ("Bedrosian reported that Lannett's chief competitor [Impax] had indeed heeded his call for price increases."). However, *Twombly* requires allegation of facts, not Plaintiffs' mischaracterizations, to state a plausible claim for conspiracy. *See Twombly*, 550 U.S. at 556.

Fourth, these analyst calls served Lannett's legitimate need as a publicly-traded company to inform shareholders, investors, and members of the public about its business operations and prospects. *Holiday Wholesale Grocery*, 231 F. Supp. 2d at 1277. The statements had a proper public purpose, *see In re Delta/Air Tran*, 733 F. Supp. 2d at 1362, and were "[p]ublic statements about [business operations]" similar to obligatory "press releases or SEC filings." *Standard Iron Works*, 639 F. Supp. 2d at 894.

The portions of the November 7, 2013 call cited in the DPP Complaint at ¶¶ 126-28 and the EPP Complaint at ¶ 112 exemplify Plaintiffs' tactics. Stripped of Plaintiffs' inflammatory mischaracterizations, here is what Mr. Bedrosian said in his opening statement to the analysts, referred to in the DPP Complaint at ¶ 127:

> The primary drivers for our outstanding first quarter performance was a combination of strong sales of existing products, a favorable product mix and price increases on key products. I'm pleased to report that we believe these positive trends will continue throughout fiscal 2014. Accordingly, we have raised our guidance for fiscal 2014.

November 7, 2013 Lannett Analyst Call Transcript at p. 3, attached hereto as Exhibit 2. This statement simply declares the obvious – very strong economic performance was driven by three factors, one of which was "price increases on key products." As the CEO of a publicly-traded company, what else could Mr. Bedrosian say?

In the DPP Complaint at ¶ 126 and the EPP Complaint at ¶ 112, Plaintiffs quote Mr. Bedrosian as saying, "[w]e've had a recent price increase on the [generic digoxin] product as well

because we are now only 1 of 2 people in the market. And I expect the product to do very well."

In context, the whole quote - a response by Mr. Bedrosian to an analyst question - reads:

> No, I wouldn't say – when you say, "lowest," I'm just not sure we're both understanding the question the right way. The brand products are usually the ones that are preferred by surgeons, let's say, and then everybody reimburses from prescriptions they prefer the generic because they have to pay for it. We still see a tremendous use of generics for this product. We don't see that changing. We do see a decline overall in the market for the Digoxin, brand and generic because the physicians that are prescribing this to new patients, these are the products that continually used on older patients, are those who already been placed on the product. And I'm presuming that because the kind of heart failure that the older people had is not the same that they are experiencing, as you know, they have made a lot of strides in preventing heart attacks. So the decline of the Digoxin in prescription volume continues every year. However, we've been successful in benefitting from the difficulties of our competitors who have left the market and as a result, our market share has continued to grow. We've had a recent price increase on the product as well because there are now only 1 of 2 people on the market. And as a result, I expect that product to do very well. We do believe some of the other competitors may come back into the market. We're anticipating that, but we're not expecting any particular difficulties with the product because they have to face their -- the ASUs and make sure that their products, when they are reintroduced in the market are not going to cause any harm. This is a very serious drug. It's a Narrow Therapeutic Index Drug, and has been allegations again some of those companies with the obese tablets that they have caused the deaths of some people. So this is a serious drug for these companies to reintroduce. So I believe that the FDA will be scrutinizing those companies very carefully. So I don't see any particular issues in that particular product going forward except a general decline in prescription volume.

Exhibit 2 at pp. 8-9. This comment is simply a statement of fact about the number of competitors in the market. It also reflects Mr. Bedrosian's expectations going forward—exactly the type of information companies are expected to provide in these calls. *See Holiday Wholesale Grocery*, 231 F. Supp. 2d at 1277.

Finally, in the DPP Complaint at ¶ 128, Plaintiffs quote Mr. Bedrosian's statement: "So these price increases that are going on in the industry, I think they're going to stick for all the companies." Significantly, Plaintiffs deliberately hide the key context around this excerpt. The full question and answer are as follows:

> Steven F. Crowley − Craig Hallum Capital Group LLC − And maybe I didn't ask it right. I was more asking about the – so I understand everything that you said, and I agree with it.

> But I was just asking more of the formularies. Have you seen any formulary pushback because of the − I think it's more than 5x price increase? Have you seen them?
>
> Arthur – ***No, you never would because their alternative is to go to the brand and the brand significantly raised their price.***
>
> Steven F. Crowley – I just wanted to make sure that didn't do a worse tiering for you guys because of that pricing.
>
> Arthur – No, no. ***We're still 50% of the brand price in the marketplace. So the alternative is to use my product or pay more and use the brand.*** They're still saving a significant amount of money and we have to face the increased cost of doing business that the FDA's going to be expecting from us when those stability studies going in effect the product development and the additional commercial batches. So those price increases that are going on in the industry, I think they are going to stick for all the companies.

Exhibit 2 at p. 9 (emphasis added).

The full question and answer show why Mr. Bedrosian believed the price increase would stick: (1) the brand name drug had significantly raised its price; and (2) Lannett was still priced at only 50% of the brand. This second observation is particularly noteworthy because Plaintiffs' own charts in the DPP Complaint at ¶ 56 and the EPP Complaint at ¶ 57 predict the average generic price in a non-collusive market to be 52% of the brand price. Thus, when read in context, the November 7, 2013 call not only fails to support Plaintiffs' claim of an agreement, but provides an "obvious alternative explanation" for the decision by Lannett, and then Impax, to raise the price of generic digoxin. *In re Ins. Brokerage*, 618 F.3d at 322 (quoting *Twombly*, 550 U.S. at 567).

The remaining calls are equally unsupportive of plaintiffs' claim of conspiracy. The February 6, 2014 call merely refers to Par, a new entry into the market, as a rational competitor and states that price increases are increasing margins. *See* DPP Compl. ¶ 129. Of more interest in that call is Mr. Bedrosian's unequivocal statement about how "I don't talk to them [Par] so I don't really know how they determine their pricing." Exhibit 3 at pp. 10-11. Plaintiffs tellingly omit this language. *See* DPP Complaint ¶ 129.

The last two analyst calls on November 3, 2014 and February 4, 2015 occurred more than a year after the digoxin price increase and merely reflect Mr. Bedrosian's views of competitors. *See* DPP Compl. ¶¶ 131-32; EPP Compl. ¶¶ 114-15. The calls do not contain any threats, hidden messages, signals or invitations. *See* November 3, 2014 and February 4, 2015 Lannett Analyst Call Transcripts, attached hereto as Exhibits 4 and 5, respectively. *See also Baraka v. McGreevey*, 481 F.3d 187, 195 (3d Cir. 2007) (court not required to accept "unsupported conclusions and unwarranted inferences").

CONCLUSION

Plaintiffs' claim that Lannett participated in a conspiracy to fix the price of digoxin fails because they plead nothing that connects their rank speculation to actual facts. Plaintiffs allege nothing demonstrating how, when or by whom the alleged conspiracy was formed. Their reliance on Lannett's earnings calls seeks to mask this failure, but these calls never went beyond the bounds of routine discussions of business operations and expectations for future performance. Nothing in the timing or content of the earnings calls lends credence to a theory of a price-fixing conspiracy dependent on these calls, either as an invitation to enter into a collusive arrangement or as a vehicle for carrying out such a scheme. And their remaining allegations assume the existence of the claimed conspiracy, characterizing innocuous events as "proof" of their claims. Plaintiffs' allegations of a price-fixing conspiracy fail under *Twombly's* plausibility standard and should therefore be dismissed.

Respectfully submitted,

/s/ Gerald E. Arth

Gerald E. Arth
Theodore H. Jobes
Ryan T. Becker
FOX ROTHSCHILD LLP
2000 Market Street, 20th Floor
Philadelphia, PA 19103

Tel: (215) 299-2000
Fax: (215) 299-2150
garth@foxrothschild.com
tjobes@foxrothschild.com
rbecker@foxrothschild.com

George G. Gordon
Stephen D. Brown
Julia Chapman
Christopher M. Trueax
DECHERT LLP
2929 Arch Street
Philadelphia, PA 19104-2808
Tel: (215) 994-2000
Fax: (215) 994-2222
george.gordon@dechert.com
stephen.brown@dechert.com
julia.chapman@dechert.com
christopher.trueax@dechert.com

Attorneys for Defendant
Lannett Company, Inc.

EXHIBIT “1”

September 10, 2013 Lannett Earnings Call

S&P CAPITAL IQ
McGRAW HILL FINANCIAL

CONTENTS

Lannett Company, Inc. NYSE:LCI

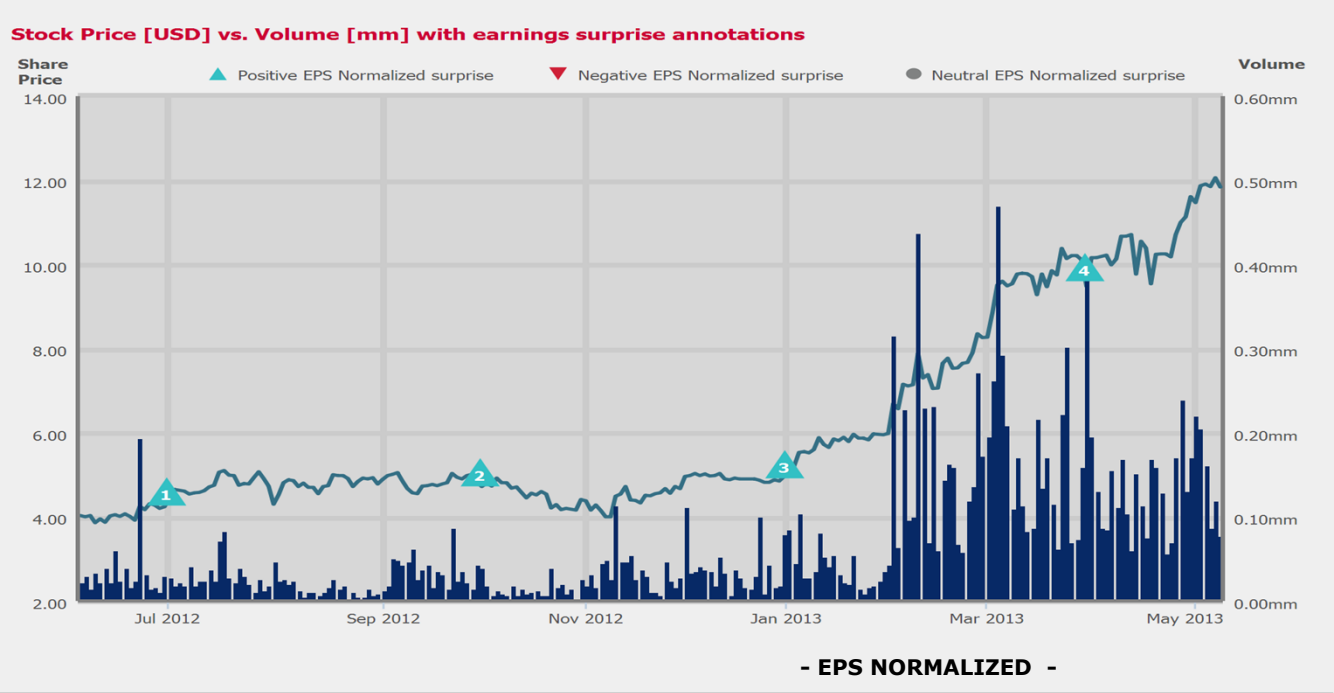
FQ4 2013 Earnings Call Transcripts

Tuesday, September 10, 2013 8:30 PM GMT

S&P Capital IQ Estimates

	-FQ4 2013-			-FQ1 2014-	-FY 2013-			-FY 2014-
	CONSENSUS	ACTUAL	SURPRISE	CONSENSUS	CONSENSUS	ACTUAL	SURPRISE	CONSENSUS
EPS Normalized	0.07	0.12	▲71.43	0.08	0.39	0.43	▲10.26	0.40
Revenue (mm)	37.89	40.17	▲6.02	39.40	148.77	151.05	▲1.53	166.71

Currency: USD
Consensus as of Aug-20-2013 12:28 PM GMT



- EPS NORMALIZED -

	CONSENSUS	ACTUAL	SURPRISE
FQ4 2012	0.04	0.06	▲1 50.00 %
FQ1 2013	0.04	0.07	▲2 40.00 %
FQ2 2013	0.08	0.10	▲3 11.11 %
FQ3 2013	0.13	0.14	▲4 7.69 %

Call Participants

EXECUTIVES

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Robert Jaffe
Principal and Senior Vice President

ANALYSTS

Dan Duong Trang
Stonegate Capital Partners, Inc., Research Division

Elliot Henry Wilbur
Needham & Company, LLC, Research Division

Randall S. Stanicky
Canaccord Genuity, Research Division

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

Steven F. Crowley
Craig-Hallum Capital Group LLC, Research Division

Presentation

Operator

Welcome to the Lannett Company Fiscal 2013 Fourth Quarter and Full Year Financial Results Conference Call. My name is Leslie, and I'll be your operator for today. [Operator Instructions] Please note that this conference is being recorded.

I will now turn the call over to Mr. Robert Jaffe. Mr. Jaffe, you may begin.

Robert Jaffe
Principal and Senior Vice President

Thanks, Leslie. Good afternoon, everyone, and thank you for joining us today to discuss Lannett Company's fiscal 2013 fourth quarter and full year financial results.

On the call today are Arthur Bedrosian, President and CEO; and Marty Galvan, our Chief Financial Officer.

This call is being broadcast live on the Internet at www.lannett.com. A playback will be available for 3 months and is accessible on Lannett's website.

I would like to make the cautionary statement and remind everyone that all of the information discussed on today's call is covered under the Safe Harbor provisions of the Litigation Reform Act. The company's discussion will include forward-looking information, reflecting management's current forecasts of certain aspects of the company's future, and actual results could differ materially from those stated or implied.

This afternoon, Arthur will provide a brief overview and Marty will discuss the financial results for the quarter and full year in more detail, followed by Arthur's concluding remarks. We will then open the call for questions.

With that said, I'll now turn the call over to Arthur Bedrosian. Arthur?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Thanks, Robert, and good afternoon, everyone. Today, I have the pleasure of reporting record results for our fiscal 2013 fourth quarter and full year. Net income for the full year more than tripled, compared with the prior year and was the highest in our company's 71-year history. We also reported record net sales for both the fourth quarter and full year.

I want to take a moment to recognize and thank all of my colleagues and co-workers for their hard work and dedication in achieving this extraordinary accomplishment.

The key drivers for our outstanding performance were the combination of sales growth across nearly all of our key product categories and higher gross margin percentage due to a favorable sales mix, price increases and efficient manufacturing. I'm pleased to report that we believe these positive trends will continue throughout fiscal 2014, which Marty will address in our guidance.

Before he reviews our financial results, I think it's important to point out that we achieved these results while continuing to invest in the company's future. This past year, we significantly increased our R&D spending by nearly 40%. We believe we enhanced our long-term prospects by expanding our product development activities to include therapies that have the opportunity to meaningfully contribute to our top and bottom line.

We also recently completed negotiations with Jerome Stevens Pharmaceuticals to extend our arrangement. Under the amended agreement, Lannett will continue to be exclusive distributor of substantially all Jerome Stevens products for an additional 5 years through March 2019. Then, signing the initial contract nearly 10 years ago, the products covered under this agreement have combined to contribute significantly to

our financial results. We're obviously pleased to continue this highly rewarding and mutually beneficial relationship with the JSP staff.

Finally, last month, we entered into an agreement to purchase 196,000 square-foot building located in Philadelphia. Our long-term plans for the facility include consolidating existing facilities and providing space for future expansion.

And with our API facility, we have been asked by the city and state to consider an expansion onto a larger site in Cody, Wyoming.

With that brief overview, I'd like to now turn the call over to Marty to review the financials in more detail. Then I will provide an operational update, and we'll open the call to questions. Marty?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Thank you, Arthur, and good afternoon, everyone. As Arthur mentioned, our positive momentum continued into the fourth quarter, resulting in excellent financial results for both the fourth quarter and the full year.

Starting with our fiscal 2013 fourth quarter results. Net sales increased 13% to $40.2 million from $35.7 million in last year's fourth quarter. I want to note that the sales growth for the most recent quarter was achieved despite no sale of oxycodone for which we soon expect FDA approval of our ANDA. We had approximately $1.5 million of oxycodone sales in last year's fourth quarter.

Gross profit rose to $15.2 million from $12.0 million in last year's fourth quarter. As a percent of net sales, gross margin rose to 38% from 34% for the fourth quarter of fiscal 2012.

R&D expense decreased modestly to $3.7 million from $4.0 million.

SG&A increased to $5.8 million from $5.4 million for the prior year fourth quarter.

Operating income more than doubled to $5.7 million from $2.6 million.

And lastly, net income attributable to Lannett increased to $3.6 million or $0.12 per diluted share, compared with $1.4 million or $0.05 per diluted share for the fiscal 2012 fourth quarter.

Turning to our fiscal 2013 full year results. Net sales increased 23% to $151 million from $123 million last year.

Net sales for our largest product category, thyroid deficiency, grew to $58.0 million or 38% of our total net sales. Our 2 other largest categories, cardiovascular and pain management, had net sales of $25.9 million and $21.2 million, respectively, representing 17% and 14% of our total net sales, respectively. As to net sales of our remaining categories: antibiotic was $9.2 million or 6% of total net sales; glaucoma was $6.4 million or 4%; gallstone was $6.1 million, equal to 4%; migraine was $5.4 million, also 4%; gout was $5.1 million or 3%; obesity was $4.7 million or 3%; and other represented $9.1 million or 7% of our total net sales.

Gross profit rose significantly to $57.4 million from $38.9 million for last year. As a percent of net sales, gross margin rose to 38% from 32% for fiscal 2012. The increase was primarily due to favorable sales mix and price increases, along with enhanced manufacturing efficiencies related to the higher sales volume.

R&D expense rose to $16.3 million from $11.8 million a year ago.

SG&A amounted to $22.4 million, up from $20.2 million for the prior year.

Operating income nearly tripled to $18.8 million from $6.9 million last year.

The effective tax rate was 35.3%, compared with 39.3% for the fiscal 2012.

Net income attributable to Lannett increased to $13.3 million or $0.46 per diluted share, which included the favorable litigation settlement of $1.3 million or $0.03 per diluted share. This compares with $3.9 million or $0.14 per diluted share for fiscal 2012.

Our balance sheet at June 30, 2013, remained strong with cash, cash equivalents and investment securities of $51.2 million.

Turning now to our guidance for the fiscal 2014 full year. As Arthur noted, we anticipate strong sales and improved gross profit, resulting from favorable sales mix, price increases and efficient manufacturing, as well as new product launches. We expect net sales in the range of $181 million to $186 million, gross margin as a percentage of net sales of approximately 43% to 44%, R&D expense in the range of $24 million to $26 million, SG&A expense ranging from $28 million to $30 million and the full year effective tax rate to be in the range of 34% to 36%.

Regarding our quarters in fiscal 2014. We expect our upcoming Q1 results to be similar to our recently completed Q4 with sequential quarterly improvement to our top and bottom line throughout the balance of fiscal 2014.

It is important to note that our guidance for fiscal 2014 does not include the impact of the shares issued in connection with the Jerome Stevens contract extension. The company intends to expense the value of the shares issued, which approximates $20 million in the first quarter of fiscal 2014. The impact of this transaction would also reduce the effective tax rate by approximately 2 percentage points.

Capital expenditures in fiscal 2014 are expected to be in the range of $28 million to $32 million, which includes $20 million for the purchase and partial fit-out related to the new facility Arthur mentioned earlier.

With that, I will now turn the call back over to Arthur.

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Thank you, Marty. I cannot be happier with our achievements and our financial performance and the progress we have made building our pipeline. As we have discussed over several quarters now, we have stepped up our product development initiatives with products that we believe can generate more revenue and higher margins than we have typically experienced in the past.

As previously reported, we have submitted our first Paragraph IV ANDA filing and additional Paragraph IV product candidates are in the later stages of development. Having received the FDA acceptance letter, we sent our first Paragraph IV notice and expect to follow with a few more in the coming fiscal year.

We continue to await approval of our oxycodone hydrochloride solution, which we expect soon.

We are laying the groundwork to expand our detailing effort for our C-Topical solution products. We expect to complete a contract that will add at least 10 additional sales representatives over the next 2 quarters. We are working closely with the FDA and expect our clinical trial to be approved by the end of this month. Preparation will begin immediately after that with trial commencement expected in the third quarter of this fiscal year. The current target to date for the ANDA submission is December 2014.

Our ANDA for thalidomide is on track for FDA filing in the fall. We were hoping to file sooner but experienced delays in receiving an API for commercial production of our exhibit batch. After completing our pilot studies, we immediately commenced our pivotal study.

We continue to evaluate several potential acquisition candidates. Our team is looking at products as well as companies that are a strategic fit and accretive to our business. Our current pipeline includes 15 product applications pending at the FDA and an additional 33 products in various stages of development.

As you can imagine, this is an exciting time for our company. We look forward to continuing to report on our progress.
Marty and I would now like to address any questions you may have. Operator?

Question and Answer

Operator

[Operator Instructions] And our first question comes from Steven Crowley with Craig-Hallum Capital.

Steven F. Crowley
Craig-Hallum Capital Group LLC, Research Division

In terms of some of the things you have a lot in the hopper, but maybe we could talk a little bit about -- your R&D budget is going to go up significantly, so you're going to continue investing in the business aggressively. Can you give us some sense for what kind of ramp we're going to see early in the year? Is it going to be over the year? Help us get the best picture you have of your intentions there.

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Yes, well, Steve, this is Marty responding. The main driver of the R&D increase in 2014 is the Phase III clinical trial for the C-Topical product. And as you know, we've been addressing that topic during fiscal 2013. The -- so the expense is in our 2014 numbers and it's the main driver of the increase and it is back end loaded, so it's more so ramping up in the second and mostly in the third and fourth quarters.

Steven F. Crowley
Craig-Hallum Capital Group LLC, Research Division

Okay. And if we think about Q1, is there's some loft between where you were in Q4 and in Q3 just based on the other things going on? Or is that a baseline that we should look at, Q4?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

I'm not quite sure of those questions. I mean, as we've said in the -- in my prepared remarks, we're looking at Q1 to be similar to Q4 in its results. And maybe you can help me with what you're looking for.

Steven F. Crowley
Craig-Hallum Capital Group LLC, Research Division

Well, I mean, there was quite a difference. You were at $3.7 million in Q4, you were $5.2 million in Q3, and I was just wondering if Q4 was kind of a natural run rate level and it appears or it sounds, I should say, likes that's the case that...

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

I'm sorry. Are you still talking...

Steven F. Crowley
Craig-Hallum Capital Group LLC, Research Division

Specifically about R&D, yes, I'm still on the R&D topic.

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

I'm sorry, I'm sorry. So -- well, yes. We were expecting R&D in the first quarter then. Okay, first of all, we said the results to be similar at the bottom line. So our expectation right now is that we expect to see that the first quarter R&D would ramp up a bit from the fourth quarter of 2013 and we expect to see that ramp up occur kind of sequentially as we go through the quarters now.

Steven F. Crowley
Craig-Hallum Capital Group LLC, Research Division

Now in terms of C-Topical, it seems like you have plans that are moving ahead on the clinical trial and on the expansion of sales and marketing activities. So I would infer that you're not really impeded from continuing to grow your sales and marketing commercial efforts while you're starting your Phase III clinical trial. Help us understand the best you can the dynamics there, and I guess, you wouldn't be adding those people if you didn't think it were appropriate in the context of everything else going on?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

This is Arthur answering the question. That's correct. From our point of view, we did a preliminary study with regards to 3 salespeople to see what the reaction would be if we detailed the product. Again, this product is used by surgeons in their practice. It's not prescribed. And as a result of the results from that 3-person initial study, we decided that adding more people into the market to detail this product at the contact surgeons would be appropriate. Our firm that we brought in to do the market research initially recommended 20 people for the entire country and we felt we'd be a little more conservative and start with 10 with the understanding that in about 6 months if we find that the 10 was not too risky, we'll probably accede to add an additional 10 people. But this is the first move for Lannett into the branding of a product. And because we don't have a lot of experience in that area, we wanted to be a little bit conservative in the engagement of all the sales reps. We would then have, with this 10 additional people, 12 out on the road, calling on the surgeons, the hospitals and introducing the product. The acceptance of the product has been so overwhelming by the physician market that we believe the only alternative for us was to put more people out on the road to let the surgeons know this product is available and to get them to include it on the formularies within the hospitals. So yes, we're pretty confident that we're making the right decisions here but doing it conservatively.

Steven F. Crowley
Craig-Hallum Capital Group LLC, Research Division

And Arthur, for you, in terms of the manufacturing expansion with the new facility, can you tell us, I guess, 2 things: how much of that capacity do you think will accommodate your near-term needs and how much headroom or extra capacity will you have for future expansion? So if we look at that 196,000 feet, how much are you likely to utilize over the near term and what's for future expansion? And what kind of additional capabilities are you looking to bring onboard or in-house with this maneuver?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Well, if you consider that we have 3 facilities in Philadelphia and that's roughly 160,000 square feet under 3 roofs, this building, this fourth building, is 196,000 by itself. And the concern is that we were originally thinking of consolidating 2 of our facilities into that. But the more we reviewed some of our needs for product development facilities and the space, the new requirements we anticipate FDA that will be introduced in the marketplace, we're now believing that we'll probably only consolidate one of our facilities into this building. So we'll still have 3 at the end of the day, and of course, more square footage. The problem right now is our sales capacity has really been reached at our manufacturing facility and what we plan to do is fit out the new building as soon as we close on the transaction. And then do it over time so that we're building into this building, which is far in excess of our needs are today, but we're anticipating what our needs are going to be as we grow. We believe this building will address that. So it's not like we're going to fit out the building all at once. We'll certainly put in the infrastructure initially and then we'll add suites and rooms as we grow. And we've already designed and brought in some firms to help us with the design. We'll be meeting with the FDA with regards to the layout of the facility as we've done in the past. We try to work with the FDA to avoid problems later. It's easier to set the stage with the local district to make sure that we're addressing any particular questions they might have about the facility, easier to plan ahead of time. So it really is going to be a manufacturing facility. It's going to be expansion of our product development facility because our plan is actually to manufacture all the products that we sell into the marketplace. We believe that's where our strengths lie. And we'll look at all the different dosage forms we might get involved in with this site. I hope that answers the question.

Steven F. Crowley

Craig-Hallum Capital Group LLC, Research Division

It certainly does. And last one for me. Marty, in terms of cash flow, it was really strong in Q4 and it looks like receivables came down a lot. Was there something anomalous going on there? And how should we think about cash flow as we move forward here?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

No, I think the -- well, thank you for giving me the opportunity to address cash flow. I mean, we had an astounding quarter in terms of free cash flow it was the strongest in many, many quarters of the history of Lannett, so we're very proud of that increase that you see in our cash, cash equivalents and investments. So very strong quarter on a free cash flow basis. The cash net income, as we refer to it, in the fourth quarter was about similar to other quarters. It's just that we then got an extra charge -- an extra benefit from the balance sheet basically and that's what drove it be even higher than in previous periods. Nothing of an anomaly there. I would say that balance sheet impact is always something of a timing nature, and things all hit well in the quarter. Of course, we're always managing our receivables down. We showed improvements there as we continue to do with the growing business. The cash management is a key concern for us. But again, just led all that to a very outstanding fourth quarter.

Operator

And our next question comes from Elliot Wilbur with Needham & Company.

Elliot Henry Wilbur
Needham & Company, LLC, Research Division

First question for Art. I suppose last quarter you had provided some preliminary color on your fiscal 2014 outlook, specifically on the top line. I think you said you're looking for kind of high single to low double-digit sales growth. Obviously, today's number for our outlook is certainly much stronger than that. Can you just talk about some of the key factors that have changed between the last time you provided guidance and now to sort of underlie your more optimistic outlook, whether it be pricing or volume trends on base generics or maybe some better visibility in terms of timing of new approvals?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Actually, the best way to answer that is we're hitting on all cylinders. All of our products are selling in larger quantities that we've ever sold them before. We've introduced our product to more customers than we have previously and those customers that we had have been purchasing more of the products. Our service levels, as you know, are quite high for the industry. So when we get an order, we fill the order. I really think it's a combination of all those things. We've rarely seen -- usually there's always some part of your business that's good, another part doesn't do so well. In this case, every part of the business have been doing very well. My compliments to my employees and my sales staff.

Elliot Henry Wilbur
Needham & Company, LLC, Research Division

Okay. And the next question for you is on C-Topical. At least in terms of the regulatory strategy and the time line for NDA filing, obviously that continues to get pushed out. And this is, obviously, your unique product in the sense that you can step up your commercial efforts in advance of the actual filing. So not as if it necessarily hurts you in the short term, but maybe can you just walk us through some of the things that are happening kind of behind the scenes on the regulatory front that are causing the extended time line on the actual NDA filing?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Well, the one that comes to mind when we submitted the final protocol, the FDA asked us to add something to it. And then when we submitted that back to them with the addition, they asked us why we

added what they asked us to add. That process -- and I know that sounds silly but that's what happened, that process took 90 days because you have to wait for letters from them. So even though we do some things by e-mail or by phone, we still had to wait for letters. So they put a clinical hold on the project to ask a question about why we added something to the protocol when they were the ones that asked us to add it to the protocol. And of course, all we had to do was say your colleague asked us to add this to protocol and that's why it's there. And once that was answered, that clinical hold that they call it, is the one they're removing the end of this month. And the clinical trial will then begin. So it's really probably more of a combination of the government, and let's say, maybe a little bit of our inexperience in this area of doing clinical trials. Generally, as a generic drug company, we don't get involved in Phase III studies. So I would say part of it was a learning curve for us, part of it was the delay that was caused by the comments from the FDA and the questions with regards to their comments. But we're on track now and I always tell people I hate to predict and use time lines when it comes to waiting on the government for something because they never really meet a time line. They respond when they respond. So I don't think we'll be incurring any more delays here. At this point, I believe we're at the end and the clinical trial will begin and there should be no further reasons for this application not to get submitted.

Elliot Henry Wilbur
Needham & Company, LLC, Research Division

Okay. And then last question for you right before I jump back into the queue here. Obviously, the M&A environment is very fluid and dynamic. And I know that on prior calls, you've talked about some potential opportunities for the company on that front and specifically 3 targets that you were evaluating. But I guess, it seems when companies like Boca can get $225 million for effectively generic version -- one generic version of Vicodin and high tech, obviously going out relatively high multiple, clearly a seller's market. So I'm just wondering how you're sort of thinking about some of these targets that you had been evaluating and sort of what you see as opportunity for the company on the M&A front here or acquisition front in the short to intermediate term?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Well, I'll admit that we are seeing some valuations. And I guess one of my fears is that maybe I might be little gun shy in spending the money I may need to spend to make an acquisition. But quite frankly, Marty won't let me do that because he reminds me how much money we have in the bank and he wants me to spend it. So we will do an acquisition. We are talking to companies. The valuation of those companies really depends on the seller and the buyer. We certainly realize there's a value and if we think we're getting value for the money, we'll make a recommendation to our board. We do have a very astute board right now and I believe they'll certainly guide us in the right direction and will certainly quiz us on the valuations. Marty and I have met with some colleagues in the industry and the best there helping us make some of these decisions. So we're planning on doing some acquisitions. We're planning on not making any mistakes with those acquisitions. And we're seeking out advice from people that have done acquisitions that can help us with the valuation. While some of the companies we've talked to have been indicated that if they were to consider, let's call it, a merger or be acquired by Lannett, they might want shares, at least that seems to be the discussion, some have said they might want money. I believe that in a scenario when someone takes stock from Lannett to be acquired, let's assume from their point of view they could have got a bigger prize, well, they're on the other side of the transaction now. If they take Lannett shares, now they're part of Lannett. Whatever bargain Lannett receives in purchasing them at a more reasonable price flows to them as well. So it's not like they're taking their cash and walking away into the sunset. So I think all the companies we've talked to really have young management teams that'll probably be helpful to Lannett in its growth. And when we make these acquisitions, I believe those management teams will want to come with us and want to see the larger company succeed. So I'm not concerned about the valuations. But when I'm looking at any companies that have risks assigned to them, similar to what you seem to be indicating where they have one product that represents the bulk of their business, these are all very substantial companies with wide product lines. No unusual products within them that are bringing in all the revenue. So I don't see any risks in purchasing them. And I believe they want to be involved with a smaller company like Lannett because they still would like to grow their businesses with Lannett. And I believe they're going to work that way and those acquisitions are going to be with these companies.

They range in size from $30 million to roughly $150 million in size. So of course, the big will mean $150 million. And there are very preliminary discussions that are going on at this point. But we continue to have discussions with them. The same people I alluded to previously, we've had additional discussions with, and a fourth one joined the group as well. So I hope we'll have some acquisitions made sometime in this fiscal year, but it depends on the seller and the buyer coming to terms.

Operator

Your next question comes from Randall Stanicky with Canaccord Genuity.

Randall S. Stanicky
Canaccord Genuity, Research Division

Arthur, can you just talk about the Levo pricing dynamics and any benefit that you've been able to capture from that as you look at 2014?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Is that a legal price?

Randall S. Stanicky
Canaccord Genuity, Research Division

No, the Levothyroxine. Yes, one of your competitors took pricing up quite significantly. I'm just wondering what your reaction was, what you've done? And as we look at the numbers, how much of a benefit could be -- could you have captured from that?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

You mean after I sent them the thank you note? I'm just kidding.

Randall S. Stanicky
Canaccord Genuity, Research Division

Exactly.

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

I'm always grateful to see responsible generic drug companies realize that our cost of doing business is going up as well. As everyone knows, the FDA has some new requirements for stability work on generic drug products that are going to cost a lot of money, you got your PDUFA fees on top of that. So whenever people start acting responsibly and raise prices as opposed to the typical spiral down of generic drug prices, I'm grateful. Because Lannett tends to be active in raising prices. We believe we have to sell our products for a price that we can make profit. That profit has to cover all the costs that we incur to make the product, as well as what we expect to incur for product development or enhancements to those products. So I'm grateful to see price increases. This particular one that was done by a competitor was -- isn't price [indiscernible] by any -- just like they do any of the price increases, we don't necessarily see the benefits right away because most of the contracts that are in place usually give the customer a buy-in period. So if you're going to raise a price on them, which is generally not the case, they have an opportunity to place an extra order. So we don't really see the benefit for usually, at least one full quarter, let's say, because there's a 60-day buy-in. So I would probably be better able to answer this when we do our guidance for our first quarter sometime in November.

Randall S. Stanicky
Canaccord Genuity, Research Division

Just going back to Elliot's question. As you look at the change over the last couple of months in your view of fiscal '14 -- 2014 revenue, I mean, it's pretty significant. So obviously, the business is doing well. You

guys are certainly executing. But is there something we can point to that's changed over the last couple of months outside of that pricing increase, whether a new product launch opportunity? Or is it confidence that you're seeing the business in part or more than in part due to the pricing opportunity there?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Well, it's really a combination. There's been a lot of products that have surprised us with their volume. One of the products was an old product of ours that we resurrected. We didn't expect to do much business with it. We didn't talk about it much a year ago because we didn't expect much. That product turned out to do, if I'm not mistaken, Marty, it was $7 million in this fiscal year. So we didn't anticipate that. We didn't think this customer would use that volume of product. So sometimes, you're a little bit surprised. Of course, we went ahead and also had to make some modifications to deal with this volume. The volume of all our products picked up as well. We have a small facility that's really running at, I hate to say capacity, but I think we've expanded the capacity in that building, so to speak. We can push the envelope. And that's why we're moving quickly to get into this other building. So I think when I say we're hitting on all cylinders, virtually all of our products are being sold in larger quantities. Our antibiotics are selling in bigger quantities. As you know, there was a bit of a hiccup and a shortage in the market when a competitor of ours closed their facility for both the doxycyline and digoxin, example. So there's opportunity to just kind of really mix together with increases in sales that really contribute overall to the success we've had this past fiscal year. And of course, strength came in the fourth quarter and now we see that continuing into this fiscal year. There were price increases last year with regards to all those products as well. So we had price increases. We had sales increases. We had additional products that we didn't have previously. We'll be launching a hopefully in about 30 days another one of our older products. Now that product we had taken off the market because the price of the product was very, very low and wasn't profitable. Now the price has experienced a dramatic increase in the marketplace so we're going to reintroduce the product. That's going to add to our guidance for this year and our overwhelming feeling that all the products are going to continue the way they have and more products are coming back into the market. We're also anticipating some approvals this year. I believe last time we talked entirely we expected about 4 products to be approved by, let's say, within the next 6 months. So that's leaning into some of our confidence in the year. So it's really been almost everything working together: applications getting approved, new products being launched in this fiscal year and price increases are just part of you might say the gravy, let's say, at that point.

Randall S. Stanicky
Canaccord Genuity, Research Division

Okay. And just one more question, somewhat related to that, for Marty. The gross margin pickup in terms of guidance next year is really solid. Should we also expect that to start to ramp as we get to the second fiscal quarter against the back half? Or could we see more of that, and I understand your EPS distribution. I'm just trying to understand the gross margin distribution. Should that ramp starting in fiscal 2Q, or can we see it right away?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Randall, that piece will also ramp up. The gross margin percentage in the first quarter is a bit higher than the fourth and -- but we do expect the more significant increase to occur in the second half of fiscal '14.

Operator

Our next question comes from Scott Henry with Roth Capital.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

I guess, to get started, Levothyroxine, things are very good right now. On the competitive front, do you have any expectations for any new competitors? Are you hearing anything about that? I'm just trying to

get an idea of, at least in the immediate to midterm, how long can we expect things to be as good as they are for Levo?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Well, I'd say not on profit. So it's always hard to say. I always -- while I'm an optimist generally speaking, when it comes to competition I always expect the worst. We certainly know that there are at least 2 possible competitors in the wings, none of them have talked about anything at this point and nothing has been approved at the agency. One is an overseas company that we know was looking for a distributor here in the United States to distribute their product. And the other one, I believe, has got an application. They're a direct manufacturer of the product. But hopefully, both companies turn out to be responsible companies and don't go into the marketplace. We're seeing more responsibility on the part of all of our competitors, I believe, because all of us are facing the same costs. PDUFA is not a cheap expense every year. I mean, every manufacturing plant has to pay that fee. The additional stability work for product development that was put off from January of 2014 to June of 2014 is going to add tremendously in terms of testing and time for each application. So I would expect that all the companies are not going to behave like they have in the past. And I suspect you're going to see more price increases in the generic marketplace or certainly less price erosion in the marketplace because of that.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

Okay, great. That's helpful. Shifting over to the pipeline and I apologize because I know you've addressed some of these questions, I just want to make sure I had it correct. On C-Topical, when is it do you expect the clinical trial to begin? And then how long do you expect the clinical trial to take? And when do you expect to file that product?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Okay. Let's work backwards. We know we'll file by December 2014. And the clinical trials we expect to start probably in January. I'm giving most conservative because most of recruiting that was done had to be stopped when the FDA put the clinical hold on the process. And of course, now that will be removed the end of this month. So now, the physicians can go out and start recruiting again. And then the actual clinical studies, the timing of it all, we're expecting to take about 6 months. Then the assembly of the data, submitting of the application we hope to get done before December of 2014. Right now, it is near the end. I don't think there's going to be any more delays that we would have not been able to anticipate. And we certainly have been working very closely with FDA for this drug and we still look forward to getting application at the agency. But I would say we're giving ourselves a year. And it is a 600-person clinical trial. So it's atypical for a final 505(b)(2) application process. And I guess, as a result, the recruiting effort that was aborted and now has to be restarted is part of that delay. Each physician has to recruit a large number of patients and do the study and then submit all that data. That's a lot of data to assemble. But here, we have some big clinical labs that we're working with, as we've mentioned before. So we're pretty sure that our application will go down the agency successfully. We're comfortable with the process.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

Okay. That's helpful. And just the rest of the pipeline, did I here you confirm thalidomide you expect to file it in the fall? Is that still the target?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Yes, that's correct.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

And then Cocaine topical, the non-FDA approved, when are we expecting that to ramp? In the past, you've given us kind of a monthly expectation.

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Well, with the sales up in September, we should have the CSO start do the hiring. They need about 2 months to do the training. So we're probably looking at a November launch, let's say, and the actual representatives out on the road, the additional 10. Two are already out on the road, for example, so then we'll go out there. So by November, those legs will be out on the road and they're only working for us with 1 product. So we're going to get a lot of attention with this product. And quite honestly, in meeting with some of the physicians myself, I have to tell you I've been astounded at their response to the value of this product. I just didn't realize how important it was to them for the physicians because it's so much better than the competing product that they use and there's nobody promoting the competing product. There are 2 old drugs that they combine to accomplish the same thing. This is superior and a quick onset. So we're comfortable that just letting the physicians know it's available, getting it on to the formularies it's just a matter of extra work, let's say, to get them market established. And then I think we're going to see some dramatic results from it. I know we're being conservative with the 10, but I'm pretty sure by 6 months we might go out and put an additional 10 people on the road if all goes according to plan.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

Okay. And then the P-IV filling, have you given us any color on the market size? How many entrants you expect out there? Or if you are, in fact, a first filer? How should we think about that and as well time line?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Well, let me say this. We've submitted the letters to them so of course they'll have 45 days to do something with the letters and the application at the agency, as you know. So until we get the product, it's hard to say how many people will be in the market at the time. But I do believe we have 2 people out there already on the market and an authorized generic. But this product in the market is very large. So we're comfortable we'll get a nice piece of the market based on our sales capability.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

And Arthur, very largely similar to subjective term, any -- could you put it in a basket? I mean, is it a $500 million product? Or how should we think about it? Any color that you can give us...

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

I believe this -- don't hold me to this, but I'm fairly sure, if you remember, this is around a $300 million market.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

Okay, perfect. Final one for you, Arthur. The Cody, Wyoming for 2014, I guess, we're looking for oxycodone. Anything else we should expect to come out of there in 2014, any signs of expansion progress there?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Well, yes. On the front of the APIs, we certainly expect to get additional APIs. They are working on the oxycodone raw material there. The Hydrocodone material, we received some material already. So we expect the emphasis to be on the active pharmaceutical ingredient front at Cody to make sure that we can vertically integrate and go ahead and achieve the goal we set for ourselves of 50% of our manufactured

products being controlled substances by 2018. So the goal is really working to continue to integrate Cody, which we have. We've addressed some of the distractions with regards to the litigation there with the former CEO. As you may or may not know, that he's not been successful in his attempts to gain any grounds, let's say. So we expect that to remain the same and the distraction now is over. The City of Cody is encouraging and I sent those letters that they're very supportive of the company, so is the community. So we continue to enjoy the support of the community out there. And the company has continued to do well. I mean, at this point, we've had a lot of inspections that we've passed, EPA included. So I'm very comfortable that our compliance record out there is matching Lannett's compliance record here in Philadelphia. So I just see them bringing more API to the market. He has a goal by June 30. I'm hoping that, that'll -- and that's all around API, that we'll achieve those goals and then we'll just add to them for the following fiscal year.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

What was that goal by 2018, 50% of manufacturing capacity? I didn't...

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

We're hoping that 50% of our manufactured products will be controlled substances. And the reason we don't use sales is because sales can be masked by price increases and what have you. Our goal is to be a controlled substance one-stop shop and the only way to achieve that is to make sure that we're filing more applications for controlled substances, using Cody as a raw material supplier so that our vertical integration and the profit margins are higher than what typically expect in the generic industry today.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

Okay, if that's the goal. Marty, if I could just hit you with quick speed around. First of all, you said EPS would be similar in first quarter to fourth quarter, which could be about $0.12 escalating thereafter. I felt when I ran through the numbers, I got to around $0.50, but if you're starting out at $0.12 and going higher, I think it would be higher than $0.50. Any thoughts? Maybe I didn't do the math right.

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Well, yes, we're not giving specific guidance on EPS numbers, Scott. The EPS -- you've got it right in terms of we think the first quarter will be similar to what we had. The results, that is, would be similar in the first quarter, similar to the fourth quarter. That is correct. And we expect to see it ramp up. Yes, I mean, you do good math. But we're not giving -- we're not going to give specifics on EPS outlooks by quarter.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

Okay, fair enough. And then the tax rate goes down a little bit. Is that a sustainable lower tax rate of 35% or just trying to get an idea of how we should think about that beyond 2014?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

That'd be the rate to use for the year 2014, that's right.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

And sustainable tax rate beyond 2014?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

We have to see how that works out. We haven't -- I mean, from Arthur's perspective, that is clearly -- clearly, the goal is to get lower than that, I'll say that.

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Yes, we are addressing the fact that we pay high tax rate as compared to some of our generic competitors. So we are addressing the reasons for it and what we can do to resolve that. So I'm hoping that certainly beyond fiscal 2014 that we'll have addressed that problem successfully.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

Okay. And then the very final question. Marty, could you -- I noticed that I didn't see an amortization line in there or product royalty line. Are those lines being shifted in the cost of goods sold? How should I think about that?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Yes, they are being shifted into the cost of goods sold. And if it's important for your modeling, we can provide that. I mean, going forward, in the Jerome Stevens, most of the amortization is almost all Jerome Stevens. So that will run out. Then come March of 2014, beyond that is just a limited amount. It's rounds to 0, the amortization expense. So you could just continue with the same amortization you've been seeing quarterly for -- for the first and second and third quarter, for that matter, of 2014. But then it stops.

Operator

Our next question comes from Rohit Vanjani with Oppenheimer.

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

So on the gross margin, is that just more of the same, it's manufacturing efficiencies, product launches, sales mix and then pricing? I mean, I kind of thought of you guys as a price follower or maybe you can kind of you go out and you take price sometimes and see if it works, but I wouldn't think that'd be embedded in guidance?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Well, I may take the steps. We're not a price follower. We tend to be a price leader on price increasing and the credit goes to my sales vice president. He takes an aggressive stance towards raising prices. He understands one of his goals, his objectives as a sales vice president is to increase profit margins for the company. And he's the first step in that process. I can reduce costs and manufacturing efficiencies, but it has to be combined with sales increase, a profit increase, as I should say, by the salespeople. And he's done a good job there. With 1 or 2 exceptions, we've tended to lead in the way of price increases. We believe that these prices are important. We need to try raising them. Sometimes, it doesn't stick and we have to go back and reduce our price, and other times it does. I am finding a climate out there has changed dramatically and I see more price increases coming from our competing -- competitors than I've seen in the past. And we're going to continue to lead. We have more price increases planned for this year within our budget. And hopefully, our competitors follow suit. If they don't, that's their issue. But our plan is to raise prices on any product that we think we can or we haven't raised a price. And our costs aren't going down. I mean, someone has to pay for these things unfortunately.

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

Okay. And then on the R&D, so I think it was $6 million or so expenses for the 600-patient trial. I think the NDA filing would cost around $2.5 million to $3 million. That's $6 million, would that bolus come

throughout the year? Is it kind of in fiscal 2Q '14? Can you give any outline on when those kind of big expenditures would come?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Yes, the bigger -- the larger piece of it, Rohit, would be in the second half of this upcoming fiscal year.

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

Okay. And then I missed the oxycodone. You're still expecting that for -- by December 2013, the approval?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Well, we're hoping for October 2013.

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

Okay. And then the FDA's announcement, that doesn't affect you guys at all, the extended release, long acting opioids? You're kind of going to be working mostly in short-acting opioids.

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

No, no, we're doing both. But we're already addressing -- we've been looking at the extended release product sometime and we have products in the works already. We weren't surprised by their decision. That was something we anticipated. But we tend to not go after the blockbuster drugs, ones that are the most popular. So that our margins are higher because we go after the products that are not on everyone's radar screen. But all of those products, because we're in the controlled substance business, will be filed by us. And we expect to file through all the extended release products as well. So you might say they're in some stage of development and product review, what have you.

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

So what did you make of what they're saying about additional studies to get to what the duration and what the dosage is? I mean, are you embedding that as part of your R&D? Or is that -- is it too early to say that kind of stuff?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

No, I mean, that's something that didn't surprise us because the FDA's attitude about being bioequivalent or being an equivalent generic in my mind means you're equal in a lot of respects. So we weren't surprised by that ruling or that guidance, you might say. So we tended to expect that early on, had it been thinking about how we make a product and instead of trying to be -- because a lot of people have offered patents to us, there's about 50 patents for extended release -- excuse me, abuse technology for extended release products. And our concern was we can't just use any of them. We have to make sure that the ones we select will make my product equal to the innovative product. So I don't see that as a handicap. I see it as part of what the FDA normally would have required. I'm not -- so I'm not surprised by it. We anticipated it and all of our actions are heading in that direction.

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

So previously, you had talked about licensing that technology or you said you were also comfortable developing your own internal abuse technology and that Cody developed one for a Hydromorphone product. Do you have any updates there on where you're leaning?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Well, we're actually doing -- we're leaning towards licensing it because the dilemma with developing our own or using the ones we've developed ourselves is that there's no guarantee. It's not pending at the patent office. For example, let's say, I used my own technology and then I get approved on my finished product by the FDA and when I go to launch it, I find out that the abuse technology I developed, someone already has a patent on it. But because it was pending, I wasn't aware of it. Now, I have a licensing issue and I can't just change to another method without refiling the product. So our thinking is let's go with a patented process, so I will eliminate that risk and I don't have to be concerned. Yes, it means licensing the technology, but we are in talks with some people and we've had modest proposals made to us for -- well, we've had immodest proposals, too, when someone offered us the technology for $25 million. And I told them I don't think we'd make that kind of profit for the drug. But generally speaking, most of the other companies are offering fees between, let's say, $400,000 to $1 million in terms of the cost for the technology and onetime costs. So we're really looking at something modest here that can be used across our products. So yes, we've been working diligently and finding. Our patent attorneys are looking at some of these patents now to make sure that the ones we purchased are strong and will survive any challenges that we would expect from the innovator companies.

Operator

Next question is from Dan Trang with Stonegate Securities.

Dan Duong Trang
Stonegate Capital Partners, Inc., Research Division

Question about the acquisitions you're going to do. Kind of wondering if you could provide some color behind kind of what's your reasoning and rationale behind what's a good candidate and what's not?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

All right, I don't want to take over troubled companies because I'm always concerned that the cost of rehabilitating them is far greater than the value to the company and when I'm looking for accretive issues. So, I mean, we look at accretive issues. So one of my goals is to make sure the companies we're looking at are attractive, no FDA problems and are accretive and they're giving me dosage forms that I believe will be more valuable going forward. So we've identified companies also that have products that fit with our goals. And you know our goal is to be vertically integrated on controlled substances. So that really starts the process. But we'll look at anything. I mean, we're not limited -- when talking about acquisitions, we're certainly looking at companies that generally fit the goal. I'm not going to look at medical device companies or brand companies or something like that, that doesn't fit the mold because I find when you don't focus on something, you end up not succeeding. We have a strategic plan. We're trying to make sure we achieve the goals in that plan and not get distracted and that means staying within the plan. The doesn't mean I'm not an opportunistic guy. It doesn't mean we won't buy a product here and there. And we are looking at opportunities to continue to sell pure generic drugs that are not controlled substances. But the emphasis on what we're going to manufacture, what we're going to submit to the agency and what we're going to get from our subsidiary in Cody, Wyoming, all tied together. But the acquisitions that we're looking at, the 4 people who I've known these companies, familiar with the ownership, familiar with their regulatory history and that's what really attracted me. Here my only concern is when someone gets them out from under me. And hopefully, they would prefer to be with Lannett than with other companies. In some cases, that seems to be the feeling on the part of the management of the other companies. They don't feel like they're going to be acquired, closed down and relocated to Philadelphia. We need the facilities. In some cases, they have facilities that are far more appropriate for what they're going to manufacture than we have and instead of me investing in those facilities, in our new facility, the new building we talked about earlier, I would just make an acquisition that would give me those facilities. And then the application at the agency would just be transferred there. So we are planning to use our common sense. And look, I'm at the end of my career, so to speak, and I need to make sure that any acquisition we make is reasonable and good one. I'm not in a position to make mistakes. So we are being careful at

the criteria we use to identify the targets. And we've started talks with 4 people. And I say talks, I want them to understand they're very preliminary just to make sure that the chemistry is right, that both sides think that this a benefit to them. Because integration is the biggest problem with all these acquisitions and mergers and you always want to make sure that you don't have those distractions to deal with. Marty has had a lot of experience in this area throughout his career. So one of the reasons we asked him to join Lannett was because he brought that with him.

Dan Duong Trang
Stonegate Capital Partners, Inc., Research Division

Okay. And number of acquisitions, are looking at only 1 for the next couple of years? Or do you not -- do you have any set number or...

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

That's what I get a little piggish. I'm actually looking at 4. Now, I don't expect to do it simultaneously, but I am looking -- because you never know which way they're going to go. Some people take a year to make up their mind about something and some make up their minds in 3 or 4 months. So I feel that with 4 of them, there's a good likelihood and I have plenty of time to make them one at a time. But I am prepared, if need be, to do 2 a time. Marty and I, as I said earlier, have been reaching out to colleagues that we can rely upon that can help us get the due diligence done quickly and effectively because we don't have a lot of experience here on hand with the exception of Marty in doing them, we want to make sure that we don't make mistakes and that we have a team we could bring in right away.

Dan Duong Trang
Stonegate Capital Partners, Inc., Research Division

Okay. So it's 4 possible -- it's 4 opportunities, not possibilities, right, that you'd ideally like to be able to acquire, am I correct?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

That's correct. And we've talked to all 4 and told them what our interests are and they're talking to us because they seem to have similar interests. So hopefully, one of them or all 4 of them will decide that Lannett is the best place to work.

Operator

We have a follow-up question from Steven Crowley with Craig-Hallum Capital.

Steven F. Crowley
Craig-Hallum Capital Group LLC, Research Division

Just 2 quick ones. I've had a chance to digest some of the revenue mix granularity that Marty gave us. And it seemed like virtually everything is going well, but one area that sticks out I'm just hoping you can address what might be behind the weakness and whether you think it's sustainable. Seemed to be that cardiovascular area and Digoxin in the fourth quarter, can you talk to us a little bit about the market dynamic there and what the outlook is?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Yes, Steve. So -- excuse me, it's a bucket of products that's cardiovascular for us. The -- and in particular, what you're seeing in the numbers is, if you'll recall, we launched back in December of 2011 this product, it's a generic Dyazide, it's Triamterene. And that product, when we first launched it, we had some particular advantages in the marketplace, which were unique at that point in time. And the product, at least in the quarter, tended to drop off a bit. That's what you're seeing -- that's the color behind the numbers I can give you.

Steven F. Crowley
Craig-Hallum Capital Group LLC, Research Division

Okay. And on the flip side, glaucoma, while relatively small, you've had a really good run, 2-year run at least of growth. And how are you thinking about the overall category of ophthalmology and your plan glaucoma can -- have we seen it kind run its course? Or is that a foundation for some bigger things in that category?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

No. As I told you, we're an opportunistic company. So we have 2 applications, 2 ophthalmitic products at the agency that we need to do a site change for because they're ready to be approved. And that's in the works. So again, this was just something we saw opportunities to make money from. Again, our goal, of course, is vertical integration of controlled substances. These are the products were developed a few years ago and we expect to launch them and I expect to sell the other glaucoma product to continue as well. So our hopes are that we'll continue to keep the business we have and grow it further. And as you know, you have an aging population. So that adds to that. You have more people needing the products.

Operator

At this time, I show no further questions. I'll turn it back to Arthur for final remarks.

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Thank you again for joining us today. We are always available to answer further questions, and look forward to reporting on our continued progress on our next call. Thank you, and have a good evening, everyone.

Operator

Thank you, ladies and gentlemen. This concludes today's conference. Thank you for participating. You may now disconnect.

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee
Thank you.

EXHIBIT “2”

November 7, 2013 Lannett Earnings Call

S&P CAPITAL IQ
McGRAW HILL FINANCIAL

CONTENTS

Lannett Company, Inc. NYSE:LCI

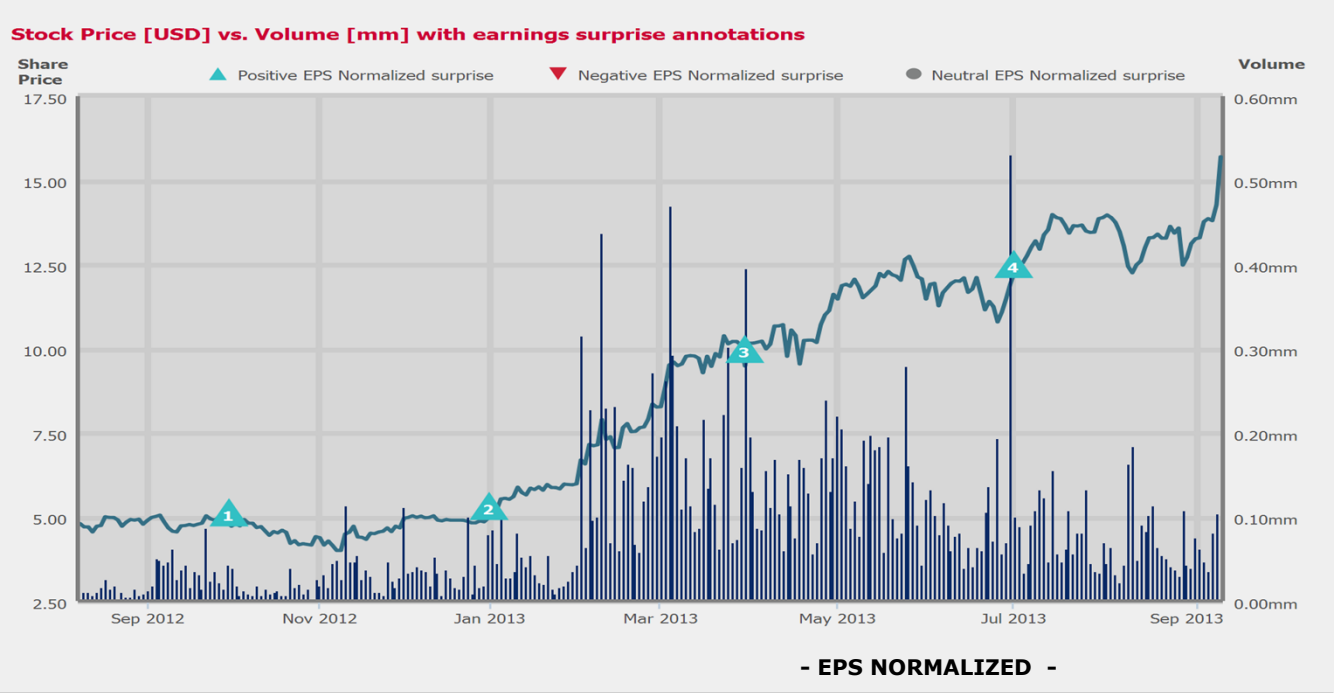
FQ1 2014 Earnings Call Transcripts

Thursday, November 07, 2013 9:30 PM GMT

S&P Capital IQ Estimates

	-FQ1 2014-			-FQ2 2014-	-FY 2014-	-FY 2015-
	CONSENSUS	ACTUAL	SURPRISE	CONSENSUS	CONSENSUS	CONSENSUS
EPS Normalized	0.21	0.22	4.76	0.14	0.64	0.96
Revenue (mm)	45.02	45.83	1.80	53.66	217.12	226.42

Currency: USD
Consensus as of Oct-31-2013 1:20 PM GMT



- EPS NORMALIZED -

	CONSENSUS	ACTUAL	SURPRISE
FQ1 2013	0.04	0.07	1 40.00 %
FQ2 2013	0.08	0.10	2 11.11 %
FQ3 2013	0.13	0.14	3 7.69 %
FQ4 2013	0.07	0.12	4 71.43 %

Call Participants

EXECUTIVES

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Robert Jaffe
Principal and Senior Vice President

ANALYSTS

Dan Duong Trang
Stonegate Capital Partners, Inc., Research Division

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

Steven F. Crowley
Craig-Hallum Capital Group LLC, Research Division

Sumant S. Kulkarni
BofA Merrill Lynch, Research Division

Presentation

Operator

Welcome to the Lannett Announces Fiscal 2014 First Quarter Financial Results Conference Call. My name is Vanessa, and I will be your operator for today's call. [Operator Instructions] Please note that this conference is being recorded. And I will now turn the call over to Robert Jaffe, Investor Relations for Lannett Company. You may begin.

Robert Jaffe
Principal and Senior Vice President

Thanks, Vanessa. Good afternoon, everyone, and thank you for joining us today to discuss Lannett Company's fiscal 2014 first quarter financial results. On the call today are Arthur Bedrosian, President and CEO; and Marty Galvan, Chief Financial Officer. This call is being broadcast live on the Internet at www.lannett.com. A playback will be available for 3 months and is accessible on Lannett's website.

I would like to make the cautionary statement and remind everyone that all of the information discussed on today's call is covered under the Safe Harbor provisions of the Litigation Reform Act. The company's discussion will include forward-looking information, reflecting management's current forecast of certain aspects of the company's future and actual results could differ materially from those stated or implied.

This afternoon, Arthur will provide a brief overview and Marty will discuss the financial results for the quarter in more detail, followed by Arthur's concluding remarks. We will then open the call for questions. With that said, I will now turn the call over to Arthur Bedrosian. Arthur?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Thanks, Robert, and good afternoon, everyone. Today, I have the pleasure of reporting another quarter of record financial results. Our positive momentum continued into our fiscal 2014 first quarter with net sales increasing 30% to $46 million from $35 million in the first quarter of last year, and excluding a charge related to the contract extension with Jerome Stevens Pharmaceuticals, our first quarter adjusted net income of $6.7 million or $0.22 per diluted share was significantly higher than expectations.

The primary drivers for our outstanding first quarter performance was a combination of strong sales of existing products, a favorable product mix and price increases on key products. I'm pleased to report that we believe these positive trends will continue throughout fiscal 2014. Accordingly, we have raised our guidance for fiscal 2014, which Marty will address in more detail shortly. With that brief overview, I'd like now to turn the call over to Marty to review the financials in more detail, then I'll provide an operational update and we'll open the call to questions. Marty?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Thank you, Arthur, and good afternoon, everyone. As Arthur mentioned, we are off to a strong start in fiscal 2014. For our first quarter, net sales rose 30% to $45.8 million from $35.3 million in last year's first quarter. Net sales for our largest product category, thyroid deficiency, grew to $20 million or 44% of our total net sales. Our 2 other largest categories, pain management and cardiovascular, had net sales of $5.2 million and $4.5 million, respectively, representing 11% and 10% of our total net sales, respectively.

As to net sales of our remaining categories: antibiotic was $3.4 million or 7% of total net sales; migraine was $2.7 million or 6%; gout was $2.0 million or 4%; glaucoma was $1.5 million or 3%; gallstone was $1.4 million equal to 3%; obesity was $1.1 million or 2%; and other represented $4.0 million or 10% of our total net sales.

As previously announced, we issued 1.5 million shares of our common stock in connection with the signing of a contract extension with Jerome Stevens Pharmaceuticals to continue as the exclusive distributor in the

United States of 3 of their products. As a result, cost of sales for the fiscal 2014 first quarter included a nonrecurring pretax charge of $20.1 million related to this contract extension.

Continuing with the remainder of the income statement and for completeness and comparative purposes, I will provide both GAAP and adjusted amounts for gross profit, operating income and net income. Gross profit on a GAAP basis was $1.3 million or 3% of net sales.

Excluding the JSP contract renewal charge, gross profit was $21.4 million or 47% of net sales. This compares with last year's first quarter gross profit of $13.6 million or 39% of net sales.

This improvement reflects an 8 percentage point increase. Research and development expenses increased to $4.7 million compared with $3.8 million. Selling, general and administrative expenses increased to $7.2 million compared with $6.2 million in the same quarter of the prior year.

Operating loss reported in accordance with GAAP was $10.6 million for the first quarter of fiscal 2014. Excluding the JSP contract renewal charge, operating income more than doubled to $9.5 million from $3.7 million in the first quarter of fiscal 2013. For the fiscal 2014 first quarter, GAAP to net loss attributable to Lannett Company was $6.0 million or $0.20 per share.

Adjusted net income, which excludes the impact of the JSP contract renewal charge, equal to $12.7 million after tax, was $6.7 million or $0.22 per diluted share. This compares with fiscal 2013 first quarter net income attributable to Lannett Company of $2.9 million or $0.10 per diluted share. Adjusted diluted earnings per share is based on approximately 30.7 million weighted average common shares outstanding.

Last year's first quarter included a favorable pretax litigation settlement of $1.3 million equal to $0.02 per diluted share.

Our balance sheet at September 30, 2013, remained strong with cash, cash equivalents and investment securities of $45.8 million. This amount does not include the $71.5 million of net proceeds related to our stock offering which was completed subsequent to quarter end.

Now turning to our guidance for our fiscal 2014 full year. As Arthur noted, we have raised our guidance for the year due to anticipated strong sales of our existing product portfolio and improved gross profit resulting from favorable sales mix and price increases. It is important to note that our guidance for fiscal 2014 does not include the impact of the Jerome Stevens contract extension, which we expensed in the first quarter of fiscal 2014. With that said, we expect net sales in the range of $245 million to $255 million, up approximately 35% from the previous guidance of $181 million to $186 million.

Gross margin as a percentage of net sales of approximately 57% to 59%, up 15 percentage points from 43% to 44%. R&D expense in the range of $27 million to $29 million, up from $24 million to $26 million in the previous guidance. SG&A expense ranging from $35 million to $37 million, up from $28 million to $30 million. And the full year effective tax rate to be in the range of 36% to 38%, up from the previous guidance of 34% to 36%.

Weighted average common shares outstanding for fiscal 2014 to be approximately 35.4 million, the increase reflecting the impact of the recently completed public offering of 4.3 million shares. Regarding our quarters in fiscal 2014, we expect a significant increase in net sales and EPS in Q2 versus Q1 and anticipate modest sequential growth in net sales and EPS through the remaining quarters.

Capital expenditures in fiscal 2014 are expected to be in the range of $28 million to $32 million, unchanged from previous guidance. The outlook includes $20 million for the purchase and partial fit out related to a new facility. In our last earnings call, we announced that we entered into an agreement to purchase a building in Philadelphia. However, we are currently exploring alternate expansion sites due to an unresolvable issue that arose during our diligence.

With that, I will now turn the call back over to Arthur.

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Thank you, Marty. I could not be happier with our financial performance and the progress we have made growing our company. As I've mentioned before, we continue to step up our product development initiatives with products that we believe can generate more revenue and higher margins than we have typically experienced historically. Accordingly, our current pipeline includes 58 product applications pending at the FDA and an additional 58 products in various stages of development, which is a significant increase from just a few months ago. We submitted our first Paragraph IV ANDA filing, which is now past the time for the innovator company to file suit, and additional Paragraph IV candidates are in the later stages of the development.

We continue to wait approval of our oxycodone hydrochloride solution which we expect in the third quarter of fiscal 2014. We continue to lay the groundwork to expand our detailing effort for our C-Topical solution products and are finalizing a contract that will add at least 10 additional sales representatives over the next 2 quarters. We expect to commence our Phase III clinical trial in January, and the target date for our new drug application submission remains December 2014.

Regarding our ANDA for the thalidomide, we have successfully passed both the fast and fed bioequivalence studies and is on track for FDA filing in the third quarter of fiscal 2014. Last month, we successfully closed on a public offering of 5.9 million shares of our common stock. The offering included 4.3 million shares offered by the company with the remaining shares offered by certain selling shareholders of the company. We received net proceeds of approximately $71.5 million and intend to use those net proceeds for potential acquisitions, strategic partnerships and general corporate purposes.

We continue to evaluate several potential acquisition candidates. Our team is looking at products, as well as companies that are a strategic fit and accretive to our business. We're extremely pleased with our first quarter results and excited about the opportunities that lie ahead. We look forward to reporting on our progress and we're grateful to the 345 employees of Lannett Company.
Marty and I would now like to address any questions you may have. Vanessa?

Question and Answer

Operator

[Operator Instructions] And our first question comes from Sumant Kulkarni with Bank of America Merrill Lynch.

Sumant S. Kulkarni
BofA Merrill Lynch, Research Division

The first one is on your significant top line guidance and please, could you perhaps break that out into how much of that is related to price increase versus some other things?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Increase in the guidance, probably a significant portion is the price increases that we've talked about previously that have now really hit us in a beneficial way.

Sumant S. Kulkarni
BofA Merrill Lynch, Research Division

And how sustainable do you think those are, especially because a large competitor could potentially return on the thyroid product sometime in the calendar first quarter of 2014?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

I believe you're referring to the innovator -- one of the innovator companies. We don't really expect them to return to the market, and if they did, we would expect them to have to put a detailing effort behind that innovator brand name because without it all the products that have been switched to other companies now. So they have to regain that market, I see that as an uphill battle for them quite, frankly. So we're not concerned about remainder of this fiscal year with regards to that product.

Sumant S. Kulkarni
BofA Merrill Lynch, Research Division

And one more before I hop back into the queue. On your growth margins, how sustainable are they beyond the fiscal quarter -- year?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

That's hard to say, but I would believe they are sustainable because we're not expecting any changes that we anticipate at this point. But we're in the commodity business, so it's always hard to determine point when you're going to get additional competition or when prices will erode as they generally do.

Operator

And our next question comes from Steven Crowley with Craig-Hallum.

Steven F. Crowley
Craig-Hallum Capital Group LLC, Research Division

In terms of the phenomenon leading up to your price increase or right after your announced price increases, there's a buy-in period in which customers can buy in, at least some of them, at prior prices. I assume given your guidance, most of that's already been reflected and you are now in the new paradigm?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

That's correct. There are a number of contracts that we have with certain customers that they can avail themselves of certain notification about any price increases. That's all been concluded now.

Steven F. Crowley
Craig-Hallum Capital Group LLC, Research Division

Excellent. Now in terms of some of your efforts in the pain management space. In terms of C-Topical and how it has been performing in the limited number of geographic markets where you've been detailing, can you talk to us about those efforts and how quickly you can bring on this contract sales force and see I guess a positive reaction to those efforts?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Well, the contract sales organization is actually engaging and hiring people at the moment. So we are moving along on that. We would expect that they'll be fielded on to the marketplace by January. And as far as whether we'll see an uptick, we're starting to find that the marketplace really wants and desires this particular product. A recent organization of ear, nose and throat surgeons actually recommended the use of the product for surgery. So we believe just by merely getting the product into the formulary of those hospitals that discontinued the powder version of this product and letting the surgeons know that the product's available if they want to use it in their practice will bring an uptick in the performance of the sales of this product that will continue. As you recall, our products have been selling well without any really effort on the part of the company to detail it. We have 2 people in a test market. We found the results to be strong enough that we felt that we increased that number to 12 to 20 people that we would see a significant uptick. And our goal now is to get that out here quickly and we are planning to make, even increase the additional 10 to an additional 18 people. So we have the full complement of 20 sales reps in the marketplace this year -- by our fiscal year end, I'm talking about.

Steven F. Crowley
Craig-Hallum Capital Group LLC, Research Division

And in terms of your guidance increase, did it include any changed assumptions in the performance the C-Topical at this point? Or if you're going to revise -- I guess, that's the question, were there any positive revisions yet to C-Topical in your guidance change?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Yes, Steve. This is Marty. So, on the guidance, at this stage we have not put in anything significant for that uplift with the detailing effort.

Steven F. Crowley
Craig-Hallum Capital Group LLC, Research Division

Okay. And then one more for me. I'll hop back in the queue. In terms of Cody, and its efforts to provide more of your API needs, what can you tell us, Arthur, about progress in objectives as we stand here today?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Well, I hate to be -- of course, we're optimistic, let's say that. They will appear to be meeting all their goals and objectives for the fiscal year ending June 30. So I'm expecting to receive 4 additional APIs that we can start to use and they seem to be on track to deliver them. So currently, I think everything is working well there at the moment.

Operator

And our next question comes from Rohit Vanjani with Oppenheimer.

Rohit Vanjani

Oppenheimer & Co. Inc., Research Division

So just a couple of modeling questions. What happened to the amortization of intangibles and product royalties lines? Is that absorbed somewhat?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Yes, we've -- it's in cost of goods sold at the stage. There is only 3 more quarters of it left, but for this fiscal year, we moved it up into that number.

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

Okay. And then is there a tax adjustment to the reported $4.242 million because of the JSP agreement?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Well, there isn't an adjustment. I mean, there is -- we talked about adjusted EPS and GAAP EPS the 4 -- or the negative $4.242 million. That's a GAAP number. So if you want to go to the adjusted number, once you pull out the charge, your adjusted number would be -- the adjusted number would be $3.202 million.

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

$3.202 million. Okay, that's what I was after. And then on the price increase for the Digoxin, have you gotten any push back from formularies or anything like that? I mean do you see that, I'm assuming it's a Tier 1 product, is that right?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

It's a Tier what -- say, Tier 1 product?

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

Yes, it's preferred tiering or the lowest tiering in a formulary plan because it's a generic. I'm guessing that's probably the case, is that true?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

No, I wouldn't say -- when you say, "lowest," I'm just not sure we're both understanding the question the right way. The brand products are usually the ones that are preferred by surgeons, let's say, and then everybody reimburses from prescriptions they prefer the generic because they have to pay for it. We still see a tremendous use of generics for this product. We don't see that changing. We do see a decline overall in the market for the Digoxin, brand and generic because the physicians that are prescribing this to new patients, these are the products that continually used on older patients, are those who already been placed on the product. And I'm presuming that because the kind of heart failure that the older people had is not the same that they are experiencing, as you know, they have made a lot of strides in preventing heart attacks. So the decline of the Digoxin in prescription volume continues every year. However, we've been successful in benefiting from the difficulties of our competitors who have left the market and as a result, our market share has continued to grow. We've had a recent price increase on the product as well because we are now only 1 of 2 people in the market. And as a result, I expect that product to do very well. We do believe some of the other competitors may come back into the market. We're anticipating that, but we're not expecting any particular difficulties with the product because they have to face their -- the ASUs and make sure that their products, when they are reintroduced in the market are not going to cause any harm. This is a very serious drug. It's a Narrow Therapeutic Index Drug, and has been allegations again some of those companies with the obese tablets that they have caused the deaths of

some people. So this is a serious drug for these companies to reintroduce. So I believe that the FDA will be scrutinizing those companies very carefully. So I don't see any particular issues in that particular product going forward except a general decline in prescription volume.

Steven F. Crowley
Craig-Hallum Capital Group LLC, Research Division

And maybe I didn't ask it right. I was more asking about the -- so I understand everything that you said, and I agree with it. But I was just asking more of the formularies. Have you seen any formulary pushback because of the -- I think it's more than 5x price increase? Have you seen them...

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

No, you never would because their alternative is to go to the brand and the brand significantly raised their price.

Steven F. Crowley
Craig-Hallum Capital Group LLC, Research Division

I just wanted to make sure that didn't to a worse tiering for you guys because of that pricing.

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

No, no. We're still 50% of the brand price in the marketplace. So the alternative is to use my product or pay more and use the brand. They're still saving a significant amount of money and we have to face the increased cost of doing business that the FDA's going to be expecting from us when those stability studies going in effect the product development and the additional commercial batches. So these price increases that are going on in the industry, I think they're going to stick for all the companies.

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

Okay. And then the last question for me and this again is on the guidance. Is that reflective -- so are future price increases also reflected in your guidance? Or is it only the price increases that you have right now on Levo and Digoxin that are primarily included in there, along with the quarterly beat that's in there?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Yes, Rohit. We had some of the price increase on Levo and Digoxin there. They are in the guidance. We've been a little bit on the conservative side in our outlook for the year only because this is the earlier days of the increase, particularly on Digoxin. So there is some of the price increases in the guidance, yes.

Operator

And we have our next question from Scott Henry with Roth Capital Partners.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

Just a couple of questions. I apologize, Marty, but could you just give me the pain, cardiovascular and thyroid numbers again. I wanted to make sure I had them correct.

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Let me just find that page here. Which one did you want, Scott? I'm sorry.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

The big 3: pain, cardiovascular and thyroid.

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

All right. So pain is $5.2 million; cardiovascular is $4.5 million; and thyroid was $20.0 million.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

Okay. I guess the next question, and I don't know if you want to give this granularity or not, but as we look at the revenue guidance, it would seem that it's heavily dependent on thyroid and perhaps cardiovascular. Could you give any color on what can of magnitude, I guess, thyroid is probably a little easier to ballpark given Q1, but how should we think about that cardiovascular section?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Well, cardiovascular, in that section there is 2 products there. First of all, it's the generic Dyazide product which we launched in December of 2011, and the other piece of it is the Digoxin product. So as far as modeling it, it's to decide on the part of the -- on your part to how much the price increase that's out there right now, to what extent it will hold and for how long. But it is the Digoxin price increase that would have a significant impact on the cardiovascular category.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

Okay. I think that's certainly fair. And then we would expect some incremental I guess in the thyroid as well, but it seems like Digoxin will be more notable in Q2. It doesn't seem like that had really any affect in Q1, is that fair?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Yes.

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Yes, that's fair.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

Okay. And I noticed the antibiotic and migraines were trending pretty strong as well. Anything going on there, timing or just simply better trends there?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

No. We expect those to continue to grow in the marketplace as well, both of them.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

Okay. I guess another kind of strategy question and particularly relevant these days, is that tax rate 36% to 38% is certainly pretty painful to stomach. Any thoughts on ideas to bring that down in the long-term? It certainly takes it's time, but would you look at trying to get assets overseas or different avenues to get that number down?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

We have looked at that. Marty and I interviewed some people that we're very expert in that particular area and we are exploring those possibilities. We understand what we need to do to qualify and it's not something we can resolve right away, unfortunately, certainly not this year. But we are actively looking to do something about that tax rate. It does pain us to know that some of our bigger competitors are paying rates that are 12% to 14% below what we're paying.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

Okay. Certainly makes sense something to follow. And just quickly on the pipeline, the Cocaine topical marketing that you were going to do, did I hear you said that, that launch would be in January?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Yes. Physically the salespeople will be on the road in January and we'll be tracking their progress from January on. The recruiting and the training is all going on now and we've had some success in finding additional information to train them on. Because apparently a recent organization of ear, nose and throat surgeons, I don't have the exact proper name handy, but I can get it to you by email, actually endorsed the use of this product. Not C-Topical, not by brand name but the use of Cocaine topical for ear, nose and throat surgery. And as a result, we expect a lot more physicians looking for information on that. And we're now training the staff to reflect that information. It's a very promising aspect. We didn't expect it and we discovered it when we attended a recent meeting of ear, nose and throat surgeons in October. So this [indiscernible] great drug.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

Okay, great. Okay, I'll look forward to that. And then it looks like the other Cocaine topical trials are on track. The thalidomide, finally, I was juggling some things earlier. Have you filed that product yet?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

No, that's -- the pass [ph] studies are done. We're assembling the applications as we speak. And it should go in the next quarter.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

Okay. So in Q1 or in Q4?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

No, in our Q -- well, we're past Q1. In our Q3 at the latest. Because of the holidays, we're a little unsure whether we'll get it in by December. So let's say, for sure, Q3 with the agency.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

Okay. That's helpful. And then I thought I heard you mention that you did submit your first Paragraph IV. Can you give us any comments about the market size for that product, how we should think about that?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Yes, that was around -- it's a little over $200 million in the marketplace. There's 2 other competitors in the market. As we were not sued by the innovator company and the patent holders, so once we get the product approved, we have clear sailing. And -- but that product is with agency now. But it is being reviewed as we speak, because we've already received some comments on it. So we know that application

should get approved. Remember on the GDUFA, they're supposed to do things quickly, and that was a GDUFA application.

Operator

[Operator Instructions] Our next question comes from Dan Trang with Stonegate Securities.

Dan Duong Trang
Stonegate Capital Partners, Inc., Research Division

Regarding the capital raise of $71.5 million, can you give any light as far as breakdown as to what you're going to spend it on or kind of time frame around that?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Yes. We were looking -- and continue to talk to 3 potential acquisition candidates. Our concern in the spring, of course, was that if we concluded any one of these transactions, we have to ask then what the cost would be to us and we felt we didn't have enough money to conclude a transaction, especially if any one of the sellers wanted to cash out. And since these were second generation companies, that was a possibility. So as a result, we felt we needed to raise money, so that if they go through with allowing us to acquire them, we wouldn't have the problem of then having to go out to find out the money and maybe not being successful. So having the money handy puts us in a better position to do some or all the acquisitions, presuming all of them are not going to want cash out. But if they did, we estimated we might need $260 million. We only had projected $50 million by June 30. So we have to do something and raising equity was one of the choice -- selling equities, of course, was one of the choices. Now we are closer and discussing one of the transactions a little in more detail, let's say, but again, we're not married yet or engaged. It's a very early stage, but we're hoping one of them will agree to merge with us and let us acquire them. And then we'll start to show you. That's really the bulk of what we wanted that money for. It wasn't for anything else other than really acquisitions that we needed before. We are looking at some product licenses. We made some offers to one of the larger generic competitors that's liquidating about 30 ANDAs. And we've put in a bid there. And that was in the substantial, let's say teens of millions, the offer was. So, we certainly knew that we're going to need money, to acquire licenses, we would need money, to do acquisitions and those were the drivers behind that raise.

Operator

And we now have a follow-up question from Sumant Kulkarni with Bank of America Merrill Lynch.

Sumant S. Kulkarni
BofA Merrill Lynch, Research Division

What level of new product launch activity have you built into this fiscal year, other than oxycodone?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

We had the anorexia prospects we talked about. We have the cytotoxic drug, we expected around February. We have another product, a pain product that the agency we expected this year and the fifth product escapes my recollection. But we were expecting 5 products to be approved by June 30 of 2014. And in a small degree they're in some of our numbers, but we tend not to make any projections until we get the approvals.

Sumant S. Kulkarni
BofA Merrill Lynch, Research Division

And this is a bigger picture question, all the stars seem to be aligning in a good way for the company, but what keeps you up at night in terms of risks?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

In terms of risks, I'll be frank with you, nothing. I don't see any -- we have so many pokers in the fireplace that any one product or any one thing really is not going to harm this company. Would we be as successful as we are today as we're sitting here today? No, of course not. But we would far and ahead of where we used to be regardless of anything terrible happening. We are cautious. We have a lot of concerns about facilities. We have -- we make sure we're complying with FDA requirements. We always try to stay ahead of those things so that we don't have to worry about them. And quite frankly, those are the things I worry about in that sense. I worry that I'm not ahead of the curve enough when it comes to compliance. We have a lot of government agencies that regulate us and we always try to make sure we are ahead of all of them. And so far, knock wood, we have maintained a very good compliance record. But I worry about never being compliant enough. It's a tough environment we're in, and the FDA is getting very tough on all companies during their normal inspections. Nothing that we can't handle, but it certainly makes me stay on my toes, let's say. But I really have to admit, there is really nothing that we worry about here. The company yes, it's a perfect alignment. A lot of things we've been saying would happen, happened finally. And it's good. And some of them happened, coincidentally, with other good things happening. For example, the company is a strong company, but having price increases on some of our products wasn't anticipated. So certainly that was beneficial to us. But I don't really see anything significant on the horizon that could cause us any pain, quite frankly. We're still conservatively run. We're still careful how we spend money. We still realize we're in a commodity business. While we're enjoying the success of the company, it's not getting to our heads in anyway.

Operator

And we have now up follow-up question from Rohit Vanjani with Oppenheimer.

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

Along those lines, just had a question on that Form 483 observations. I think you sent the resolutions in mid-August. Have you received the response from the FDA or is there an exit interview expected in near timeline? Or when do you expect the conclusion of that?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

No, unfortunately, with their furlough -- they were part of the furlough, so they lost a lot of time and this district is very busy. So we don't really know when they're going to come around. We've tried to anticipate that and contact them, but they don't know themselves when they're going to be able to follow up. We do believe our responses were very strong though and there wasn't much room for controversy as we were following up on all agreements we made. So if they were to come in for an exit interview, they'll find everything we told them we're going to do we've undertaken to do or completed already.

Operator

And we have no further questions at this time. I will now turn the call over to Mr. Bedrosian for closing remarks.

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Well thank you, again, for joining us today. We're always available to answer further questions and look forward to reporting on our continued progress on our next call. Thank you, everyone.

Operator
And thank you, ladies and gentlemen. This concludes today's conference. Thank you for participating. You may now disconnect.

EXHIBIT “3”

February 6, 2014 Lannett Earnings Call

S&P CAPITAL IQ
McGRAW HILL FINANCIAL

CONTENTS

Lannett Company, Inc. NYSE:LCI

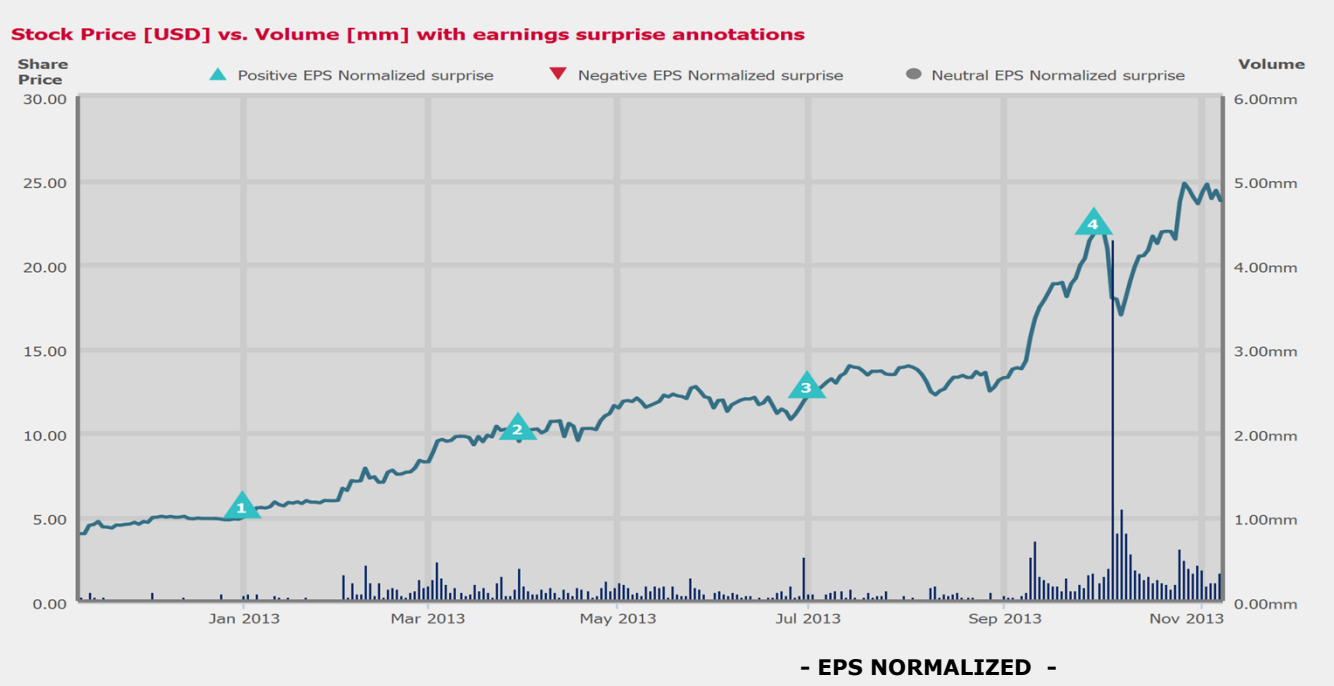
FQ2 2014 Earnings Call Transcripts

Thursday, February 06, 2014 9:30 PM GMT

S&P Capital IQ Estimates

	-FQ2 2014-			-FQ3 2014-	-FY 2014-	-FY 2015-
	CONSENSUS	ACTUAL	SURPRISE	CONSENSUS	CONSENSUS	CONSENSUS
EPS Normalized	0.35	0.46	31.43	0.40	1.35	1.64
Revenue (mm)	62.21	67.33	8.23	68.93	248.64	283.98

Currency: USD
Consensus as of Feb-04-2014 10:15 AM GMT



- EPS NORMALIZED -

	CONSENSUS	ACTUAL	SURPRISE
FQ2 2013	0.08	0.10	1 11.11 %
FQ3 2013	0.13	0.14	2 7.69 %
FQ4 2013	0.07	0.12	3 71.43 %
FQ1 2014	0.21	0.22	4 4.76 %

Call Participants

EXECUTIVES

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Robert Jaffe
Principal and Senior Vice President

ANALYSTS

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

Steven F. Crowley
Craig-Hallum Capital Group LLC, Research Division

Sumant S. Kulkarni
BofA Merrill Lynch, Research Division

Presentation

Operator

Welcome to the Lannett announces fiscal 2014 second quarter financial results. My name is John, and I'll be your operator for today's call. [Operator Instructions] Please note that this conference is being recorded.

I will now turn the call over to Mr. Robert Jaffe, Investor Relations for Lannett. Mr. Jaffe, you may begin.

Robert Jaffe
Principal and Senior Vice President

Thanks, John. Good afternoon, everyone, and thank you for joining us today to discuss Lannett Company's Fiscal 2014 Second Quarter Financial Results.

On the call today are Arthur Bedrosian, President and CEO; and Marty Galvan, Chief Financial Officer. This call is being broadcast live at www.lannett.com. A playback will be available for 3 months on Lannett's website.

I would like to make the cautionary statement and remind everyone that all of the information discussed on today's call is covered under the Safe Harbor provisions of the Litigation Reform Act. The company's discussion will include forward-looking information reflecting management's current forecast of certain aspects of the company's future, and actual results could differ materially from those stated or implied.

This afternoon, Arthur will provide a brief overview and Marty will discuss the financial results for the quarter in more detail, followed by Arthur's concluding remarks. We will then open the call for questions.

With that said, I will now turn the call over to Arthur Bedrosian. Arthur?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Thanks, Robert, and good afternoon, everyone. I am pleased to report outstanding financial results for the quarter. For the fiscal 2014 second quarter, we recorded the highest net sales, gross margin and net income in our company's history. Net sales increased 84% to $67 million. Gross margin more than tripled. And net income grew to $17 million, which was nearly 6x the net income we recorded in last year's second quarter. We are pleased to have reported 5 consecutive quarters of record sales.

Similar to the preceding quarter, the primary drivers for our excellent second quarter performance were the combination of price increases on key products, strong sales of existing products and a favorable product mix. We have seen the strength in our first quarter continue into the second quarter. And as a result, we are increasing our fiscal 2014 guidance, which Marty will address later.

With that brief overview, I'd like now to turn the call over to Marty to review the financials in more detail, then I will provide an operational update and we'll open the call to questions. Marty?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Thank you, Arthur, and good afternoon, everyone. As Arthur mentioned, our strong momentum from the beginning of the year continued into the second quarter. This is our eighth consecutive quarter of growth over prior year for net sales and adjusted EPS.

For our second quarter, net sales rose 84% to $67.3 million from $36.6 million in last year's second quarter. Net sales for our largest product category, thyroid deficiency, grew to $26.2 million or 39% of our total net sales.

Our 2 other largest categories, cardiovascular and pain management, had net sales of $16.9 million and $6.8 million, respectively, representing 25% and 10% of our total net sales, respectively. As to net sales of

our remaining categories, antibiotic was $4.3 million or 6% of total net sales; migraine was $2.3 million or 3%; gout was $2.0 million or 3%; glaucoma was $1.5 million or 2% of total net sales; gallstone was $1.1 million, equal to 2%; obesity was $844,000 or 1%; and other represented $5.2 million or 8% of our total net sales.

Gross profit more than tripled to $41.0 million or 61% of net sales, from $13.4 million or 37% of net sales. Research and development expenses increased to $5.8 million compared with $3.6 million. Selling, general and administrative expenses increased to $9.9 million compared with $5.2 million in the same quarter of the prior year. Operating income grew markedly to $25.4 million from $4.7 million in the second quarter of fiscal 2013. The net income attributable to Lannett Company grew sixfold to $16.6 million or $0.46 per diluted share from $2.9 million or $0.10 per diluted share.

Now comparing the first half of fiscal 2014 with the first half of fiscal 2013. Net sales rose 57% to $113.2 million from $71.9 million in the prior year. With respect to cost of sales, and as previously announced, we issued 1.5 million shares of our common stock in connection with the signing of the contract extension with Jerome Stevens Pharmaceuticals to continue as the exclusive distributor in the United States of 3 of their products. As a result, cost of sales for the first 6 months of fiscal 2014 included a nonrecurring pretax charge of $20.1 million related to this contract extension.

Continuing with the remainder of the income statement and for completeness and comparative purposes, I will provide both GAAP and adjusted amounts for gross profit, operating income and net income. Gross profit on a GAAP basis was $42.3 million or 37% of net sales. Excluding the JSP contract renewal charge, gross profit was $62.4 million or 55% of net sales. This compares with last year's first half gross profit of $27.0 million or 38% of net sales. R&D expenses increased to $10.5 million from $7.3 million. SG&A expenses increased to $17.1 million from $11.3 million. Operating income reported in accordance with GAAP was $14.7 million. Excluding the JSP contract renewal charge, operating income was $34.8 million compared with $8.4 million in the fiscal 2013.

GAAP net income attributable to Lannett Company was $10.6 million or $0.31 per diluted share. Adjusted net income, which excludes the impact of the JSP contract renewal charge equal to $12.6 million after tax, was $23.2 million or $0.69 per diluted share. This compares with fiscal 2013 first half net income attributable to Lannett Company of $5.8 million or $0.20 per diluted share.

The first 6 months of last year included a favorable pretax litigation settlement of $1.3 million equal to $0.03 per diluted share. Our balance sheet at December 31, 2013, strengthened compared to June 30, 2013, with cash, cash equivalents and investment securities totaling $105.9 million. This amount includes $71.5 million of net proceeds related to our stock offering, which was completed in October of 2013.

Turning now to our guidance for the fiscal 2014 full year. As Arthur noted, we have raised our guidance again for the fiscal year. The increase is due to the continuing effects of both price increases and strong sales of our existing product portfolio. In addition, we expect continued improvement in gross profit resulting from the price increases, strong sales and favorable sales mix. It is important to note that our fiscal 2014 guidance does not include the impact of the Jerome Stevens contract extension, which we expensed in the first quarter of fiscal 2014.

With that said, we expect net sales in the range of $275 million to $285 million, up approximately 12% from the previous guidance of $245 million to $255 million. Gross margin as a percentage of net sales of approximately 61% to 63%, up 4 percentage points from 57% to 59%. R&D expense in the range of $30 million to $32 million, up from $27 million to $29 million in the previous guidance. SG&A expense ranging from $39 million to $41 million, up from $35 million to $37 million. The full year effective tax rate to be in the range of 36% to 38%, unchanged from previous guidance.

And capital expenditures in fiscal 2014 are expected to be in the range of $28 million to $32 million, unchanged from previous guidance and includes $15 million for the purchase and partial fit-out of 2 buildings recently acquired by the company.

With that, I will now turn the call back over to Arthur.

Arthur P. Bedrosian

Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Thank you, Marty. Our financial performance has been tremendous with 5 consecutive quarters of record sales. In addition, we hit a market cap of $1.3 billion and began trading in December on the New York Stock Exchange. To fund our future growth, we completed a successful stock offering, raising more than $70 million and established a $50 million credit facility. Considering all these accomplishments, we believe Lannett's future is very bright.

As I have mentioned before, we continue to invest in our product development initiatives. These efforts include products that we believe can generate more revenue and higher margins than we have typically experienced historically. Our current pipeline includes 17 product applications pending at FDA. We have an additional 55 products in various stages of development, including our ANDA for thalidomide, which we expect to file momentarily. Regarding our oxycodone oral solution, we are optimistic that we will receive FDA approval in the current fiscal year.

We currently have 12 sales representatives detailing our C-Topical solution product. We commenced our Phase III clinical trial in January and the target date for our new drug application submission remains December 2014.

We continue to evaluate several potential acquisition candidates. Our team is looking at products, as well as companies that are a strategic fit and accretive to our business. We completed the acquisition of 2 buildings in Philadelphia. Our long-term plans for the site include consolidating existing facilities and providing space for future expansion.

We are extremely pleased with our second quarter results, and I would like to take this opportunity to thank all of our staff at each of our locations for their hard work in helping us achieve these excellent results. I would especially like to express my appreciation to our sales team for a job well done, as well as for the support from our shareholders. All of us at Lannett are excited about the opportunity that lie ahead, and we look forward to reporting on our progress.
Marty and I would now like to address any questions you may have. Operator?

Question and Answer

Operator

[Operator Instructions] Our first question comes from Sumant Kulkarni from Bank of America Merrill Lynch.

Sumant S. Kulkarni
BofA Merrill Lynch, Research Division

The first one is, could you comment on the sustainability of your gross margins going forward? And also, on the main therapeutic areas that contributed to the increase in the outlook range?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

On the outlook range? The main products that -- I wasn't clear on the last part. The main products for the outlook range?

Sumant S. Kulkarni
BofA Merrill Lynch, Research Division

Yes. So the gross margin outlook range is higher now relative to when you last issued it. So which were the main products that contributed to that delta?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Okay.

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Yes. So Sumant, this is Marty. So as far as the sustainability of the gross margin, the outlook, what we have in our guidance right now is -- let me comment -- we have -- we projected in terms of our second -- in terms of our third and fourth quarters, we have -- we see sales in the third quarter being a bit higher than the fourth quarter in the guidance. And consistent with that, we have a stronger, a slightly stronger gross margin in the third quarter than we have in our projections for the fourth. Now the reason for that is that as we sit here today we have, obviously, better visibility into the next 2 months, let's say, of our fiscal third quarter. And that gross margin we feel reasonably comfortable with. We've taken a conservative look or we've kind of positioned our guidance conservatively for the fourth quarter because we have less visibility, let's just say, and we are anticipating -- in some major products, we're anticipating that the success that we're having will draw other competitors and that is in our guidance. Going beyond that though, when you look into 2015, at least, right now, from our perspective, we think that the gross margin that we have in our fourth quarter, we think we can reasonably sustain that into fiscal 2015. The key products -- the larger products on which we've seen significant price increases, we've kept those outlook in 2015 and our thinking to be conservative at this stage. We've allowed for competitors to come in. But right now, as we stand, we think we can sustain that fourth quarter gross margin into fiscal 2015. And as far as I think the other part, Arthur, was the key products? Is that right, the key products? Well, the key products that are driving it from a -- driving our gross margin from a price increase perspective, the key ones from a magnitude perspective are the Levothyroxine Sodium product and also Digoxin. But I also must say that we have been able to increase prices on more than just those 2 products and it's the portfolio of products and their price increases which is driving that gross margin that you see.

Sumant S. Kulkarni
BofA Merrill Lynch, Research Division

And specifically on the thyroid deficiency products, given that Pfizer's Levoxyl is now showing up as available on the FDA's drug shortage website, should we think about that as growing in the second half of the year from this base of $26 million that you reported this quarter or shrinking?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

I see their market probably increasing but at the expense of Synthroid, because Synthroid seems to have benefited from the removal of Levoxyl from the marketplace. Synthroid sales revenues grew dramatically. And we believe a lot of the brand business from Levoxyl went to AbbVie's Synthroid product. So we just see that shifting back, possibly to Pfizer, although I think Synthroid, or AbbVie, will probably be able to hold on to most of that revenue increase. So we don't see it impacting our business. The more emphasis there is on brand in the marketplace the better it is for us.

Sumant S. Kulkarni
BofA Merrill Lynch, Research Division

And my last one before I jump back into the queue is a bigger picture one. Now that the stock has done well and your cash position has built up, have the goal posts for your acquisition targets changed at all?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

No. We're actually talking to the same people we started talking to. That we felt that we would need to raise funds if we went ahead and acquired one or all of them. We'll continue to talk to the same group with one addition. So there's a lot of discussions going on, but there's what we would call dating at this point. Nobody's kissing anybody just yet.

Operator

Our next question comes from Scott Henry from Roth Capital.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

I guess just a background question first, just as far as expectations. Obviously, the stock has had a very strong run, and I imagine that management has somewhat of a considerably concentrated wealth in the company at this point. Should we expect to see normal diversification over the coming months, perhaps some 10b-5 plans? Just trying to understand what expectations there should be.

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Sure. Thanks, Scott, for the question. That's true. Several members of the board and management have stock options that were granted about 10 years ago and are set to expire in May of this year. In the coming months, we may see transactions involving the exercise of some or all of these stock options, which total approximately 100,000 shares. I'm certainly happy that our stock price has increased so these options have value. I'm also pleased that the members of the board and management waited to just before these options were set to expire, before exercising the options. I think that speaks to our collective belief that Lannett's common stock represents an attractive long-term investment. I'm part of this group, and intend to sell enough options to cover the tax liability related to the options and hold on to the rest.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

Okay. Shifting gears to a couple more specific questions. First in the Digoxin market. I mean, we've got this Lanoxin coming in from Par, I guess, it's an authorized generic of Covis' product. Are you seeing any impact in that? I'm not seeing any impact on the prescriptions yet. And what are your expectations for how that product will do in terms of market share and how it will impact the category?

Arthur P. Bedrosian

Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Well, we've estimated -- of course, we're getting these estimates from our sales team. We feel we'll probably have some reduction in units. We're not sure of the exact amount, but I would say it would be less than 20% in terms of the total market. So we don't see a big impact on us personally. But we were anticipating it in the marketplace. There's really not much harm that it's going to do to our expectations because that's all baked into our guidance at this point. We do know that Covis, which acquired the brand with GSK, has been -- has selected Par as an authorized generic. And we see Par as one of our rational competitors in the marketplace. So we believe they'll capture a certain market share, as will Covis, because they'll probably put a little bit of an emphasis behind the brand. But sometimes when they put some movement behind the brand, it actually expands the generic market as well. So again, we're always conservative when we give our guidances out, and we believe we've more than anticipated any impact this will have on us on the Digoxin sales.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

Okay. And then you're looking at the quarterly progression throughout the year to get to your new guidance of $275 million to $285 million. I mean, it looks like we're probably going to get a boost of around $10 million in Q3 and maybe $20 million in Q4. Is the main driver there continuing to be kind of annualization of these Digoxin price increases? Or I'm just trying to think, sequentially, what is driving the increase? Could it be some of the oxycodone solution? What are the main levers for the rest of the year?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Scott, let me just address that. First of all, just to calibrate here. If you take a look at our full year outlook and the guidance, the midpoint, the $280 million, we see the second half of the year -- we see the revenue for the second half of the year in the third and fourth quarters being fairly similar but skewed more to the third quarter. And so what happens when you look sequentially from the second, third and to the fourth quarter, the second quarter -- the actual results essentially do not reflect the full impact of what's going on within our business, let's say, essentially the price increases, which is the significant part of the growth as you go from the first to the second and on through the quarters. So in the third quarter is, really, the first quarter where you will see the full impact of the price increases. So there's more of a step change in our numbers going from the second quarter to the third quarter. And in fact, the fourth quarter actually comes down a bit in our guidance expectation. And what's driving that essentially is that, okay, as I mentioned earlier, we have good visibility now for the remainder of this third quarter that we're in. And again, the third quarter has the full impact of the price increases. So the third quarter is our strongest quarter in our outlook for the entire 4 quarters of 2014. And then we've actually in our guidance have dropped our third -- our fourth quarter, I'm sorry, dropped our fourth quarter a bit, because we are just expecting that the success that we've had will draw competition. We have -- we believe we've factored in all the competition we know of right now in our numbers. But I think as we've been doing here at Lannett, we've basically been -- we work with guidance on a more conservative basis, if you will. And to that extent, like I said, we have our fourth quarter dropping a bit from the third quarter. And it's basically driven by the thought that there'll be other competitors in the marketplace that we don't know of today.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

Okay. I appreciate that color. And I guess that leads into another question. Just in broad terms when we think about 2015, obviously, you've got some -- you have some positive levers. You have new products and you have Q1, which will be an easy comp, and part of Q2 will be an easy comp. But you will have more competition. So when we think about 2015, factoring all that in, do we think of that as an up year, a flat year or possibly even a slight decline year? I'm just trying to think of how you think about 2015 without looking for any specific numbers.

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Right. Well, we see it as an up year. We do believe strongly that there's sustainability in some of the price increases that we've been -- that we are seeing right now that are in our third quarter numbers from a guidance perspective. We feel pretty comfortable with those price increases. A couple of the main products, be it Digoxin and Levothyroxine, we've been conservative in our outlook when we look at 2015. But if you take the fourth quarter of 2014 as a launch point into 2015's quarters, we see growth and we also see -- and then also, you'll have the effect that in 2014, we didn't have the price increases for the full year. So 2015 in our mind starts looking along the lines of an annualization of the fourth quarter of 2014. And as I said, we have the fourth quarter sales dropping a little bit from the third quarter, but both third and fourth quarters are in the same ballpark.

Operator

Our next question comes from Steven Crowley from Craig-Hallum Capital.

Steven F. Crowley
Craig-Hallum Capital Group LLC, Research Division

In terms of some of the elements in the future, in terms of C-Topical and the experience your sales force is having with the product, maybe you could give us some color on that. I know it's early, but some color would be helpful. And the applications that seem to be emerging to drive the utilization of that product.

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Okay. First of all, it's easy to answer the second question first. There are new applications for which this product seems to be ideal, that has to do with the balloon sinuplasty, and also the eustachian tube-plasty that they're doing now as well. Everybody's laughing at me because I finally pronounced eustachian correctly. That's a little slight joke here. And so out of the last -- the product is doing well and those 2 areas are new areas for the product. We've had some contacts with the people that sell the balloons themselves, so there's a little bit of cooperation going on there. As far as the product and the detail for us, we just launched, around January 16, I think, was the launch dinner. So they've just been on the road a little bit. We're certainly getting some good feedback and we're still very encouraged by the effort that we're putting into that. So much so that even though we don't have any, let's say, preliminary results, we're starting to fill in for the other 8 positions. Originally we were suggesting 20 people. We have 12 out on the road. We are starting to recruit for the other 8. So we're a bit optimistic on that whole opportunity. Again, we have no experience in the brand market so, clearly, we don't have a lot of history to fall back on and we are relying on a lot of advisers in that field. But we're pretty comfortable this is going to be a great drug for us, and we've also seemed to have found another companion product for post-operative surgery that we might be able to detail to the same surgeons that we're offering this product to, which would make the whole concept of the detail more profitable. The goal is to always have more than 1 product to offer. So that's going good so far.

Steven F. Crowley
Craig-Hallum Capital Group LLC, Research Division

Is that something you've acquired, Arthur, or in-licensed that product or you're in the process of doing so?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

No. It's an idea we had for one of our products and we would be filing a suitability petition to see if the FDA agrees that we could file this as an ANDA under one of our already existing applications. It would just be a lower dose of one of the narcotic products.

Steven F. Crowley
Craig-Hallum Capital Group LLC, Research Division

Excellent. Now in terms of your ANDA filing plans, you might have touched on this, you said you had a number at the agency, a number in development. What's a realistic, maybe slightly conservatively colored objective for ANDA filings out of your group this year?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Well, we've earmarked -- our goal is to file, this is a very unusual year for us as you'll all understand, our normal expectation is around 14 applications to 16. We pushed the envelope and asked our staff to get 30 applications to the agency. With that being the total goal, we're certainly very optimistic that between 25 and 30 may achieve that goal. We rely on a lot of third-party people, suppliers and what have you, so any one of them could certainly delay any of these applications. But as we speak today, we are certainly thinking we'll have filed 25 ANDAs with the agency by June 30 of this year. That would be a huge accomplishment for a company our size.

Steven F. Crowley
Craig-Hallum Capital Group LLC, Research Division

Absolutely. Now just one more for me. In terms of oxy and your confidence in finally getting that through the logjam. And in a strange way, the delay in timing might actually work for you from a comparison standpoint because it sounds like you're hoping by the end of the year and that would put it in play to relaunch for early next year. Is that the right kind of expectation for us to have? And what gives you some confidence that, that might actually happen this go-round?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Well, first of all, this is a best guess of my regulatory staff. We feel, at this point, there's probably up to 4 applications that are just ready to be approved. We're doing our best; we've engaged Washington counsel to deal with this problem. Sometimes we turn to the Ombudsman, there's a number of -- well, they're actually Ombudswoman at the agency that we're turning to, to find out why these products are being delayed and what we can do about it. Apparently, we're not the only people complaining about these delays. It's really a lack of transparency that we're complaining about. It's not like I want to be moved out of the queue. I'll stay in line, but I'd like to know how long the line is. And we're certainly trying to get that information. But I'm always the optimist here. And I still believe that within this fiscal year, we will get at least 3 of the 5 that I said we should get this year. I originally was hoping for 5. I've curtailed that to 3 of the applications. There's just nothing else left to be done with them. So we think the logjam will break up shortly, and I am expecting them in the fourth quarter for sure. But you said correctly, that, that probably would be a benefit to us picking up those additional revenues in the next fiscal year.

Operator

Our next question comes from Rohit Vanjani from Oppenheimer.

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

So on Digoxin you said that Par is a rational competitor. Are you seeing anything on the pricing front from them in terms of discounting?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Well, discounting to our price, no. We've seen their prices discounted to the brand, of course, but we're not troubled by their pricing in the marketplace. Not at all.

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

Okay. So you think it's in line with yours and they've followed suit in terms of that price increase?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

It's hard to say what's in line. It's not doing us any harm, but I don't know how you describe what's in line. I don't talk to them, so I don't really know how they determine their pricing. But remember, they're distributing a product as well and they certainly don't want to harm the brand market for which they are offering the authorized generic. So I believe that restrains them. And that's not hurting us. The prices that they're quoting are not doing us any harm at all.

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

Okay. And then are you seeing any other competitors come out in Digoxin this year?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

We don't expect any in the short term at all at this point. One of them we know is at least a year away. I don't want to identify names, but -- so there is one that possibly could be, but they're not talking about it. So that always leads me to believe they're not ready to enter the marketplace. So I'm expecting that 2 additional competitors probably entering the field next fiscal year. So sometime after July.

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

Okay. And then just to drill down on the guidance a little bit. Was that -- so is the revenue take-up, is that where you're baking in more on the price increase on Levo and Digoxin or migraine? Is that all now baked in or is it now -- is there still some left over, I guess, or can you say?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

So for the third quarter, the price increase we currently have or the pricing levels we currently have, that's in our guidance for the third quarter. It's in the fourth quarter where we've been a little bit conservative. And like I said, I actually brought down the sales outlook in the fourth as compared to the third quarter.

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

Okay. And then the pipeline products, are they at all included in guidance or -- I guess, you're saying it's now 3 out of the 5 that will be in fiscal 2014, will those add to sales in that fiscal fourth quarter or not really substantially?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Not significantly. Because we'd only have 1 quarter at best, and nobody is sitting with an empty shelf waiting for us. So I would say it would have no impact on this fiscal year at all, even if we got them before the fiscal year was over.

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

Okay. And the oxycodone product, that will be fiscal 2015 now or is that still fiscal 2014 with no appreciable sales?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Just to be -- to clear, Rohit, we do have a modest amount of oxycodone in our fourth quarter at this stage and then it continues on into 2015.

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

Okay. So you're still expecting approval this fiscal year?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Yes. Yes.

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

That's one of the 3 of the 5 -- the 3 products that you originally had? Or out of the 5 products, you're now saying 3, oxycodone is in that 3?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

That's correct.

Operator

[Operator Instructions] We have no further questions at this time.

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Thank you again for joining us today. We're always available to answer further questions and look forward to reporting on our continued progress on our next call.

Operator
Thank you, ladies and gentlemen. This concludes today's conference. Thank you for participating. You may now disconnect.

EXHIBIT “4”

November 3, 2014 Lannett Earnings Call

S&P CAPITAL IQ
McGRAW HILL FINANCIAL

CONTENTS

Lannett Company, Inc. NYSE:LCI

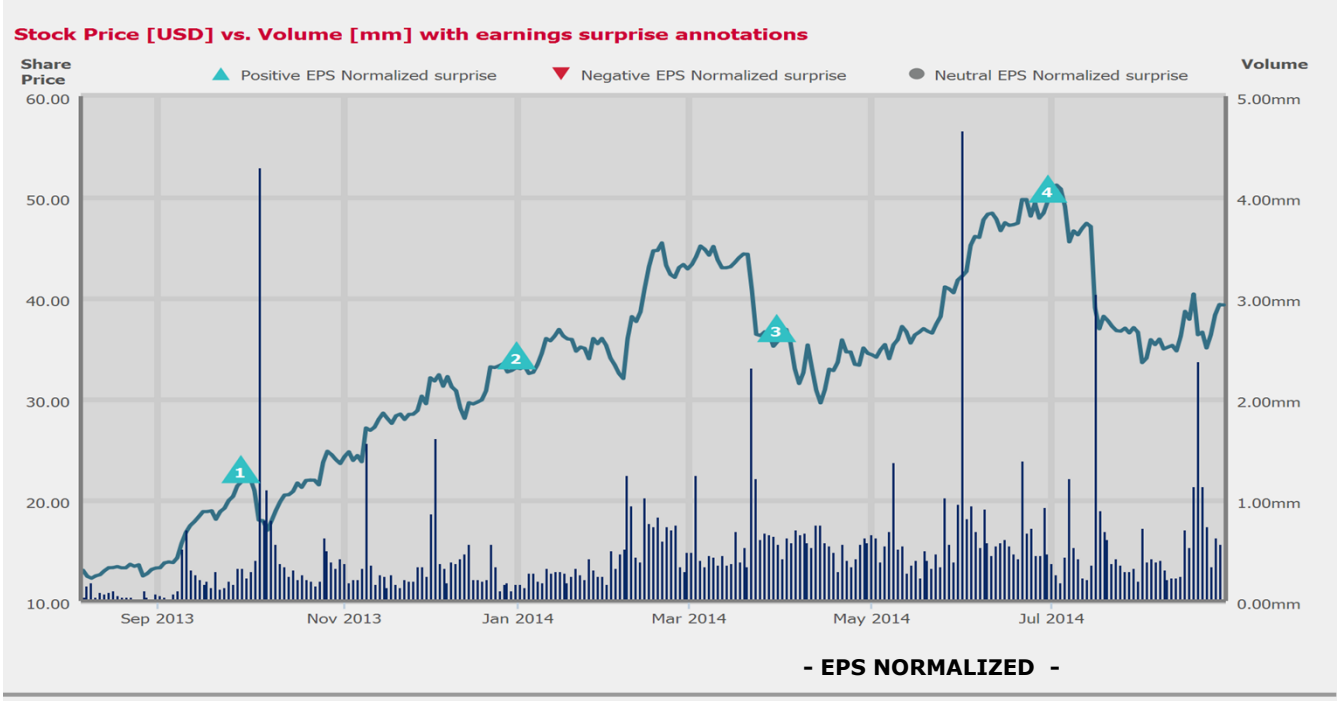
FQ1 2015 Earnings Call Transcripts

Monday, November 03, 2014 9:30 PM GMT

S&P Capital IQ Estimates

	-FQ1 2015-			-FQ2 2015-	-FY 2015-	-FY 2016-
	CONSENSUS	ACTUAL	SURPRISE	CONSENSUS	CONSENSUS	CONSENSUS
EPS Normalized	0.81	0.94	16.05	0.71	2.88	2.98
Revenue (mm)	93.24	93.39	0.16	89.40	357.92	394.15

Currency: USD
Consensus as of Oct-23-2014 7:57 PM GMT



- EPS NORMALIZED -

	CONSENSUS	ACTUAL	SURPRISE
FQ1 2014	0.21	0.22	4.76 %
FQ2 2014	0.35	0.46	31.43 %
FQ3 2014	0.61	0.63	3.28 %
FQ4 2014	0.62	0.64	3.23 %

Call Participants

EXECUTIVES

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Robert Jaffe
Principal and Senior Vice President

ANALYSTS

Elliot Henry Wilbur
Needham & Company, LLC, Research Division

John L. Newman
Canaccord Genuity, Research Division

Matthew Gregory Hewitt
Craig-Hallum Capital Group LLC, Research Division

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

Presentation

Operator

Welcome to the Lannett Company's Fiscal 2015 First Quarter Financial Results Conference Call. My name is Vivian, and I'll be your operator for today's call. [Operator Instructions] Please note that this conference is being recorded. I will now turn the call over to Mr. Robert Jaffe. Mr. Jaffe, you may begin.

Robert Jaffe
Principal and Senior Vice President

Thanks, Vivian. Good afternoon, everyone, and thank you for joining us today to discuss Lannett Company's Fiscal 2015 First Quarter Financial Results. On the call today are Arthur Bedrosian, President and CEO; and Marty Galvan, Chief Financial Officer.

This call is being broadcast live at www.lannett.com, and a playback will be available for 3 months on Lannett's website.

I'd like to make the cautionary statement and remind everyone that all of the information discussed on today's call is covered under the Safe Harbor provisions of the Litigation Reform Act.

The company's discussion will include forward-looking information reflecting management's current forecast of certain aspects of the company's future, and actual results could differ materially from those stated or implied.

This afternoon, Arthur will provide a brief overview, and Marty will discuss the financial results for the quarter in more detail, followed by Arthur's concluding remarks. We will then open the call for questions.

With that said, I'll now turn the call over to Arthur Bedrosian. Arthur?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Thanks, Robert, and good afternoon, everyone. I hope you enjoyed our latest theme song, Here We Go Again by Whitesnake, an appropriate beginning to our Q1 conference call.

I'm happy to report that we have an exceptional quarter, driven by strong sales across multiple product categories, as well as significant increase in gross margin. For the fiscal 2015 first quarter, we recorded the highest net sales, gross margin and net income in our country's -- company's history, with net sales of $93 million, gross margin of 77% and net income of $35 million, equal to $0.94 per diluted share.

We have now reported 8 consecutive quarters of record net sales, as well as the 11th consecutive quarter in which net sales and adjusted earnings per share exceeded the comparable prior year period.

Our outlook for fiscal 2015 remains strong. And with the excellent performance of the first quarter now under our belt, we have raised our full year guidance, which Marty will discuss in more detail shortly.

With that brief overview, I'd like now to turn the call over to Marty to review the financials, then I'll provide an update, and we'll open the call to questions. Marty?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Thank you, Arthur, and good afternoon, everyone. As Arthur mentioned, we reported an outstanding fiscal 2015 1st quarter. For our first quarter, net sales more than doubled to $93.4 million from $45.8 million in last year's first quarter.

Net sales for our largest pharma category, thyroid deficiency, grew to $33.3 million or 36% of our total net sales. Our 2 other largest categories, cardiovascular and gallstone, had net sales of $18.9 million and $11.8 million, respectively, representing 20% and 13% of our total net sales, respectively.

As to net sales of our remaining categories, pain management was $6.7 million; migraine was $5.8 million; glaucoma was $4.7 million; antibiotic was $3.0 million; gout was $2.3 million; obesity was $915,000; and other represented $6.0 million.

Continuing with the remainder of the income statement and for completeness and comparative purposes, I will provide both GAAP and adjusted amounts for gross profit, operating income and net income for last year's first quarter.

As you recall, in last year's first quarter, we issued 1.5 million shares of our common stock in connection with the signing of a contract extension with Jerome Stevens Pharmaceuticals. Accordingly, cost of sales for the fiscal 2014 first quarter included a nonrecurring pretax charge of $20.1 million related to this contract extension.

Gross profit was $71.6 million or 77% of net sales. This compares with fiscal 2014 first quarter adjusted gross profit of $21.4 million or 47% of net sales. GAAP gross profit last year was $1.3 million or 3% of net sales.

Research and development expenses increased to $6.4 million compared with $4.7 million in the same quarter of the prior year. Selling, general and administrative expenses increased to $10.6 million compared with $7.2 million.

Operating income was $54.7 million versus a GAAP operating loss of $10.6 million and adjusted operating income of $9.5 million in the first quarter of last year.

Net income attributable to Lannett was $34.9 million or $0.94 per diluted share. This compares to a net loss attributable to Lannett Company of $6.0 million or $0.20 per share and adjusted net income of $6.7 million or $0.22 per diluted share for the first quarter of fiscal 2014.

Our balance sheet at September 30, 2014, remains strong, with cash, cash equivalents and investment securities totaling $152.3 million.

Turning now to our guidance. We have raised our guidance for the full year fiscal 2015 as follows: Net sales in the range of $370 million to $390 million, up 6% from previous guidance of $350 million to $370 million; gross margin as a percentage of net sales of approximately 73% to 75%, up from 70% to 72%; R&D expense in the range of $34 million to $36 million, down from previous guidance of $36 million to $38 million; SG&A expense ranging from $46 million to $48 million, down from $47 million to $49 million; the full year effective tax rate to be in the range of 36% to 38%, unchanged from previous guidance.

Regarding the phasing of quarters in fiscal 2015, in the second quarter, we anticipate net sales to increase compared to Q1. Q2 gross margin percentage decreases slightly compared to Q1, while operating expenses increase primarily due to an increase in R&D expense. As a result, we expect Q2 EPS to be similar to Q1.

In the second half, we expect net sales for each quarter to be similar to the first quarter. However, increased operating expenses are expected to result in lower EPS compared to the first half.

Capital expenditures in fiscal 2015 in the range of $40 million to $50 million, which includes $7 million to continue the partial fit out of the 2 buildings recently acquired by the company. This is unchanged from previous guidance.

And with that, I will now turn the call back over to Arthur.

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Thank you, Marty. For the quarter, we recorded strong sales across a number of product categories, including cardiovascular, gallstone, glaucoma, migraine and thyroid deficiency. We also benefited from increased sales of our C-Topical and recently launched Oxycodone Hydrochloride Oral Solution product.

Digoxin sales remained steady compared with sales in our fiscal 2014 fourth quarter. As we discussed in our last call, we took a conservative approach in estimating fiscal 2015 sales of this product after a medical abstract was published. We advised that the study results may not have an impact, and as it turned out, they did not.

As we previously discussed, the Attorney General's Office of the State of Connecticut requested information on the pricing of Digoxin. We have responded to all of the Attorney General's questions to date and firmly believe we have acted in full compliance with all applicable laws and regulations. We have also responded to an information request from a U.S. congressional committee on generic drug prices.

We believe our company is positioned for continued growth and success. The alliances we have formed are in various stages of development or marketing. And on the business development and M&A front, we continue to seek out acquisition opportunities for both products and companies.

We have a pipeline of companies we're in some stage of negotiation, and while I cannot predict when or if a transaction will close, I remain optimistic. Our team continues to look at opportunities that are a strategic fit and accretive to our business. We are particularly interested in opportunities to globalize and further vertically integrate our operations. In addition, we are focused on potential acquisition and a tax-favorable jurisdiction to enhance shareholder value.

Last week, we announced the approval of Letrozole. This is the third FDA approval we have received thus far in fiscal 2015. While total sales of Letrozole are significant, we are a late entry into the market, having filed the ANDA in June of 2010.

This morning, we announced positive results from an FDA inspection of our Cody Labs subsidiary. After a thorough investigation and inspection, we received only one minor 483 observation. I'd like to acknowledge our Cody team for their dedication and high standard of quality and excellence.

We continue to increase our pipeline. We currently have 21 ANDAs, including 5 with Paragraph IV certifications pending at the FDA. Of our additional 43 products in various stages of development, we expect to submit several additional product application in the near future, and our plans call for continued significant investments in R&D.

With regard to our C-Topical solution product, we have targeted December of this year to submit our New Drug Application. However, due to minor delays in the recruitment of patients, we are revising the filing date of our New Drug Application to mid-year calendar 2015.

We have been invited and expect to present at several upcoming investor conferences, including the Credit Suisse Healthcare Conference in Phoenix next week; the Jefferies conference in London in mid-November; the Oppenheimer conference in New York in December; the Guggenheim conference in Boston, also in December; and the JPMorgan conference in San Francisco in January.

I want to thank our Board of Directors and my 400 colleagues for doing an outstanding job, and to our shareholders who have continued to support our efforts. We continue to be very positive about Lannett's future.
Marty and I would now like to address any questions you may have. Operator?

Question and Answer

Operator

[Operator Instructions] And our first question comes from Matt Hewitt.

Matthew Gregory Hewitt
Craig-Hallum Capital Group LLC, Research Division

I was hoping to ask a few questions about some of the recent developments, specifically related to the Letrozole approval, the Oxy approval and then the 2 products you acquired, just kind of going down that list. With the Letrozole, did you have inventory at risk? I mean, are you going to be able to launch that immediately? And if so, how quickly do you think you can get up to a normalized market share? I know that there's a number of other competitors, but your share of that, I mean, is that going to be a couple of quarters or maybe take a little bit longer than that?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Well, first of all, no risk to any inventory, and we expect to launch, probably gain market in the last 2 quarters of this fiscal year.

Matthew Gregory Hewitt
Craig-Hallum Capital Group LLC, Research Division

Okay. And then regarding, I guess, the 2 products you acquired, are those tech transfers done yet? And if so, have you relaunched or when do you think that will occur?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Well, actually, 1 of the 2 -- well, there's no tech transfers needed to be waited on because the company agreed to manufacture the product for us while the tech transfers were occurring. So that's not being delayed. One of the products I think we said would be launched this year, the other one we didn't give a date for, and at this sitting, I don't have the date for the other product either.

Matthew Gregory Hewitt
Craig-Hallum Capital Group LLC, Research Division

Okay. But once you are able to get those transferred, I would assume there would be a gross margin benefit to getting those done, correct?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Well, you're saying would it add to our gross profit margins?

Matthew Gregory Hewitt
Craig-Hallum Capital Group LLC, Research Division

Correct.

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

I think we're at such a high level, I don't know if it would really add to it, just probably stay within the same range.

Matthew Gregory Hewitt
Craig-Hallum Capital Group LLC, Research Division

Okay. And then maybe one follow-up from me and then I'll jump back in queue. Regarding your gross margin, you guys are extremely high. Bravo on that front. But as you start to launch additional products, is it safe to assume that that's going to come in, and granted you have higher sales, so the gross profit should remain similar, if not go up, but the gross margin percentage should come down as you are launching additional products, correct?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

That's about right, Matt. This is Marty. So yes, I mean, we would expect newer products to come on at lower than these levels. We have the full year guidance out there, and although we increased it, it is still lower than where we are today. And that just reflects the evolution of the company, newer price coming on it'd be hard to think that we maintain the pace we're going at in terms of gross margin percentage.

Operator

And our next question comes from John from Canaccord.

John L. Newman
Canaccord Genuity, Research Division

Just had a general question in terms of taking up the guidance for the year. What were the main components in that? Was it the new product launches that you have because of the ANDA approvals? Are you seeing things on the pricing side that you hadn't expected? Or is it -- is a lot of it from just the sort of rollout that you've had or sort of the -- sorry, the continued sales strength you've had with Digoxin?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Yes, well, John, it's several things. It's first of all, we are seeing volume increases. We're having some -- or seeing some good volume increases, for example, out of Levothyroxine, actually. The -- but in addition to that, we are -- we have been, as you know, we have been conservative, and we said that particularly with projecting out Digoxin and second of all, Ursodiol, the 2 products we've talked about price increases, these 2 products now for the last 2 conference calls. So on Digoxin, we are feeling a bit more confident now than we were at the end of August when we did our last call. And Ursodiol, too, we're holding that back from a guidance perspective because we were unclear as to how long that multiple-fold increase in price would continue forth. So with both products, we'll continue -- we feel more positive now and more confident.

John L. Newman
Canaccord Genuity, Research Division

Okay. And also, Arthur, you sort of made comments over time about the longevity and the time line ahead in terms of being able to continue to take up price on some of your larger products. Can you give us any kind of a sense as to how much longer you think, for example, you can continue to raise price on Digoxin and Levo? I know there's a lot of factors that go into that, but I'm just curious as to sort of how much more time you think there is before it becomes a little bit more challenging?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Well, on the Digoxin, if we just look at the mechanics, we're at 25% of the brand. So Digoxin could be increased to 50% to 75% of the brand where, of course, 75% being the limit. In the case of Levo, we're already at 75% of the innovator brand. So unless they advance their product pricing further, we're kind of stuck where we are in the Levo. And in the case of Digoxin, it is under consideration as far as whether we have further increases on it. But what Marty is trying to say is those 2 products alone don't really account for everything. We're getting price increases on a lot of products in our line. And to part of your question as to how long do I think this will last, I have told some shareholders previously in the conferences that in my opinion, the end of 2016, calendar 2016, I tend to think some of these price increases will start to decline. I do see what I'm calling the patent cliff panic where people are not seeing any growth in their revenues because they don't have any period of exclusivity looking to capture market share by lowering

prices. And also the consolidation that goes on in the marketplace certainly doesn't help. So from my perspective, what we're seeing here is an opportunity to raise prices because everybody has accepted the fact that our costs are going up dramatically and less concern about grabbing market share. We're all interest in making a profit, not how many units we sell. So it's really a combination of those things. So I don't think Levo and Digoxin are the only products I would sit here and tell you I could raise prices on because I believe any of the products in our product line, including products that we may have just gotten approved, have those same opportunities underlying them. We look at the market and sometimes, we're the first ones to raise the price, sometimes we're not. But we look at everything in our line as a potential product to have a price increase on. And again, it's during this period of time where there have been shortages, there have been a lot of reasons for these price increases that are coming about, and most of it are tied to our increased costs going forward to be in the generic drugs space.

Operator

And our next question comes from Elliot from Needham & Company.

Elliot Henry Wilbur
Needham & Company, LLC, Research Division

Just a couple of additional questions on the top line and revised guidance. What would you characterize as the biggest swing factors between the low end of current guidance and the upper end of the revised range? I mean, it would seem, sort of given the pricing dynamics in Ursodiol and Digoxin and Levothyroxine, that further upward movement in those products is probably unlikely over the balance of the year, so I'm just trying to get a sense of the $390 million, like how conservative is that in terms of adding in some maybe some additional new product launches that you didn't factor in when you gave the guidance originally?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

So Elliot, this is Marty. So the -- I would think the more significant pieces are in the upsides in the existing products, probably the same 2 we mentioned earlier on this call, Digoxin and Ursodiol. We've still held back a bit in our outlook with the 2 products are not completely clear yet. So those are the 2 big drivers of the range, I would say. Levothyroxine, we feel pretty good about our projections for that, so we don't see that as a big swing item, not right now. But it's still would be on those 2 products, Digoxin and Ursodiol. The new products could come in, but we've been fairly conservative in our outlook for the new products. They're not going to get out there early enough and then -- and they're not going to be out there in a significant enough volume early on to have a great impact on our results for fiscal 2015. So it's those 2 products, the 2 existing products.

Elliot Henry Wilbur
Needham & Company, LLC, Research Division

Okay. And maybe we could just get Art to comment on the expectations for increased competition in both of those product categories. I know on Digoxin, we've been talking for some time about West-Ward reintroducing -- reentering the market in a more significant fashion and maybe Caraco at some point as well, although that situation is pretty unclear. But maybe more recently, Mylan recently got an approval out of their Puerto Rican facility, although they've been pretty quiet in terms of launch. Just wondering what's your sort of thinking there over the balance of the year in terms of the competitive environment. And also on Ursodiol, I think you talked last quarter that you sort of expected the current dynamics to kind of play out over the next 3 quarters or so. I'm just sort of wondering if that's still your expectation.

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Last first, yes, the Ursodiol, we still expect the product to produce strong earnings and sales for us this year. With regards to the Digoxin market, we haven't really experienced Mylan's entry, but Mylan is one of those rational competitors, so we're not really expecting anything crazy from them. I believe what Mylan will do will pick up this space that we have predicted West-Ward would probably grab, when I thought

that they would launch around June, July of this year, and haven't. Caraco still remains unknown. It would appear that since they're closing down Detroit, that product may not be on the front burner for them. Of course, in the meantime, Sun acquired Ranbaxy. So I think there's a lot more important issues in front of some pharmaceutical than launching Digoxin. So that really leaves the Par Pharmaceutical authorized generic, the innovative products, Mylan and ourselves and Impax. And I believe that all of the negative news that came out about Digoxin, which caused us to be very conservative in our outlook for the first quarter, didn't materialize. And now we're more comfortable that we'll see a strong sales for Digoxin throughout the rest of the year, with the unknown, of course, of when West-Ward and Caraco should jump in. But at this point in time, we're not hearing anything about them. So we're going to discount the fact that those 2 will come into play, and we are expecting Mylan to come in. And this is one of those cases where each one of us has our favorite customers and usually, we get business to start with from our customers that prefer doing business to one company versus another. No major change in either one of the Levos, Digoxins for the year, though.

Elliot Henry Wilbur
Needham & Company, LLC, Research Division

Okay, fair enough. And let me just ask you one last question here as well on the M&A environment. And I know you made some comments earlier about still evaluating some potential targets, and I think there's a couple of things that maybe you've been looking at for a while. Obviously, it's a sellers' market and just wondering from your perspective if you think there's really still -- if it's still possible to find good values out there or you're just simply paying fair market value and it just happens with relatively high PEs and low cost of capital that the transaction still would have been highly accretive. And just wondering along those lines as well, given that it's a seller market, if you're starting to see a lot more assets coming to the fold in terms of small private companies looking to exit or bigger books of business from larger pharma companies may need to put on the -- being put on the block just because the valuations are so attractive.

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Well, that's true. I mean, first of all, looking at the companies we're looking at, I'm not going to sit here and tell you we're underpaying for any of them by any stretch. We're certainly being fair in the marketplace and valuing them the same way any of my competitors would value them if I intend to purchase them. So -- and that is a challenge in itself. Yes, we've also been having a lot of companies thrown at us, usually companies that there's no buyer anyplace else and they try to throw it at you as an inversion target, so they take -- I'll use the example of a $30 million company they want to sell to me for $300 million so I could do an inversion, and our attitude is no thank you. We are looking at a target for an inversion where they make sense, even if there was no inversion. And that's what really drives us, what makes sense. With regards to some of the other valuations, there's a company out there asking north of $2 billion. We personally think it's worth $500 million, and we certainly would look at it at $500 million. But at $2 billion, we're not interested. So there is a lot of stuff being tossed at us. But quite frankly, I don't think it's wise to jump into the fray, make those rash or irrational decisions to overpay for something, and then wake up 8 months from now and realize how we're ever going to pay back the shareholders for this payment we just made for this acquisition. So I think we're being conservative is the way we are with our earnings releases and looking at each one of the acquisitions. But we're still talking deeply with some of them, so we're going beyond just the talking stage, and I would characterize it as we're going beyond kissing as well so that hopefully, we conclude a transaction. But as you all know, in the mergers and acquisitions world, a lot of stuff comes up when you're doing your due diligences, when you're negotiating and you have to get past all those hurdles. We believe we will close on a transaction soon, and we believe it will be accretive as we promised, and the shareholders should be happy with our approach.

Operator

And our next question comes from Scott from Roth Capital.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

A few questions. Marty, I didn't catch the thyroid number for the quarter, if you could just give that to me again?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Sure. It's $33.3 million.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

Okay, great. And if I heard correct, cardiovascular was $18.9 million?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

$18.9 million, correct.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

Okay. Now we should -- I believe that would be the high watermark for the year. Should we expect that number to trend downward significantly? Or how should we think about that sequentially through the year?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Well, that is predominantly Digoxin, I think everyone understands that. The -- we have -- in our own guidance, we've trended it down through the remaining quarters of fiscal 2015. And yes, we did increase the number -- full year number as compared to the last earnings call. We did increase it because, as we kind of alluded to earlier, we're feeling more confident in the outlook for fiscal 2015 for Digoxin. But yes, it trends down $2 million or $3 million each quarter sequentially.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

Okay. I believe originally, you had kind of trended it down 10% for potential risk from the JACC article. Have you completely removed that haircut from your forecast at this point?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Yes, we have, we have at this stage. The last earnings call, we talked about a number of about $35 million. We are characterizing it is about 10% or less than 10% of our fiscal 2015 revenue. That number now we have taken up -- we've taken it up by about $10 million to about $45 million for the year.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

Okay, great. That's very helpful. And I just had a couple of other questions on the segments. The gallstone, $11.8 million, should we think of it as a representative number? I mean, obviously, it jumped a lot and we were expecting that. Is that kind of the new normal?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Well, this is the Ursodiol product. And right now, we expect that we'll see more of the price -- but it's already been implemented as a price increase, so we'll see more of that materialize in the second quarter, and we're also seeing some good volume in that particular category. So...

Scott Robert Henry

Roth Capital Partners, LLC, Research Division

So it could go up from here?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Yes, we expect it to go up. Correct.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

Okay, that's helpful. And just the final segment that jumped out to me, pain, $6.7 million, hasn't really kind of been as robust as some of the others. Should we start to see more of a notable growth in that segment?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

The -- well, the pain category is primarily driven by the C-Topical product. We also have now -- you'll see in that category oxycodone coming in, in our second quarter, based on the approval. So you should see that product category pick up a bit -- well, in both products. C-Topical is doing well, so you'd expect an uptake there into the second quarter. And you'll see numbers now for oxycodone, which we haven't had, as you know, in the past or -- and hasn't been in our -- it was a minimal amount in our first quarter, our fiscal first quarter.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

Okay. And I guess a general question. I mean, we've seen these layers of price increases coming in, Levo, Digoxin, Ursodiol. Is there a fourth one in that list we should be thinking about? Or I know, you're seeing everywhere, but are there any that are reaching the material level that we should be factoring into our numbers?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

No. I would say no. I mean, we have others, a second tier, which are becoming -- could become significant, but right now, no, these are -- we have been talking about the main products.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

Okay. And then maybe a question for Arthur, and this is a challenging question. But obviously, generics is a competitive industry. And as we've seen these markets evolve, growing in magnitudes of higher level, one would think it would attract more competition. The question I would have, Arthur, is are you seeing that start -- the seeds of that starting to play out? Or what kind of duration should we think of these relatively stable markets at higher prices? Is this a 3-year thing, a 5-year thing, how do you think about that?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Well, as I said earlier, I'm thinking it's going to be -- it will have turned out to be 4 years if I'm correct because I'm predicting by calendar -- end of calendar year 2016 that this will change and the opposite will occur. The larger generic companies will be looking to see growth. They won't be getting it from periods of exclusivity, so their next reaction most likely will be to grab market share, and that usually means lowering price. So when you look back, if I'm right and it's the end of 2016, it would have been roughly 4 years of price increases that have held steady -- or climb, I should say. So let's just say that the rocket ship is leveling off now that it's broken through the atmosphere.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

And then what do you do...

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Scott, Marty wants to answer that.

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

To that I would just add that the other important -- the other very important factor to consider with Lannett is that, as you know, the strategy for the company, it's never been to build Lannett based on price increases. This has been more of a phenomena that's occurred over the last couple of years, let's say. The strategy's always been focused on pain, focused on controlled substances and vertical integration. So in our mind, when we look out over the years, as much as we see prices coming down in time, as Arthur says, is if we look at our strategic plan, it's just about as those price increases are coming down or decreasing you then start seeing the product portfolio of Lannett shift more to controlled substances and at that higher margin that we do enjoy today from the controlled substance products. So it's as the price decreases occur in, say, 2016, in that time frame, at the same time, you then be able -- you're able to see the shift, the distinct shift in our product portfolio as we grow to more than 50% of our manufactured products being in controlled substances. So we see that -- so the products -- we don't get hurt as much as you might think from the product price -- the price decreases because that is offset as I've just explained.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

So when we think about that, if it plays out the way you think it will play out, and it may or may not, do you think you could -- when it comes around to 2017, do you think you could offset any declines with gains in controlled substances and other categories?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Yes, that's correct. So the way we kind of look at it is that, say, from a gross margin perspective, as margins start coming down from the levels we're at now, that 70% -- above 70%, let's say, as they start dropping, we see our gross margins actually plateauing somewhere in that, say, 55% to 60% range because as the, let's say, today's portfolio starts dropping, say, it should go below 50% or something of that nature, there is an offset, and the offset is that the product mix of Lannett at higher margins in the controlled substance base offsets that decrease. And in fact, from our own modeling, we think we level off into the -- 4, 5, 6 years now, we're leveling off at that 60-plus range in terms of gross margin.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

Okay, okay. And then we're nearing the final questions here. But obviously, your one area for net income growth could be lower taxes. Inversions, as they were 6 months ago, don't appear as simple. I guess, what are some of the things -- I mean, can you take assets offshore? I guess the question is, how low can you get that tax rate away from, say, the 37%, 38%, and how long will it take, given the new dynamics?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Well, first of all, some of those changes that were made to the potential for inversions really didn't impact the kind of plans we had, and some of the atypical inversions weren't impacted as well. So I think you're reading more into what they've said in the papers as opposed to when you look at the change that they made, it really doesn't impact it. So we still continue to believe that an inversion makes sense, but the target we've chosen also makes sense even if there was no inversion at all. And we all look at globalizing

the company, which, as Marty has pointed out to me, offers a lot of other opportunities to start to reduce your tax concerns here in the United States, which puts us in an uncompetitive situation when you're trying to be a global player. So we think we could address those things simultaneously with trying to increase our controlled substances to offset the profits we've been realizing on price increases so that the company has a stable basis for growth, that no one's going to sit there and go, well, what if this and what if that. In other words, there'd be so many avenues that we would have explored that we would be at a safe mode in terms of our growth and our profits.

Operator

And our next question comes from Rohit from Oppenheimer.

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

So just on the pieces of guidance, to confirm, Marty, you're not valuing -- besides Oxycodone, you're not valuing much of anything. Is that still true?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

It's at a low number, yes.

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

It's at a low number. So you said you took up Digoxin by $10 million from $35 million to $45 million. I think Ursodiol you were at $25 million and then the bulk of it, you took that up by close to $10 million and then that's the majority of it, the guidance? Or something close to $35 million?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Well, Ursodiol, we had up at $35 million. Actually, back in the last guidance, the 2 iterations ago we were talking about, run rate, annual run rate of $50 million for the product based on the 10 quarters. Price increase at 2 quarter -- 2 earnings calls prior, we put that at $25 million saying, hey...

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

Right, then you took it up at $35 million. Right, my fault. Right. And so you took it up to something like $40 million or $45 million for this quarter?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

We took it up to like $50-ish million by vote, by vote.

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

And then, Arthur, I think you were saying for Mylan, you thought about the entry in October. I haven't seen scripts for that yet. Are you still thinking -- are you still characterizing that entry as imminent for Digoxin?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

So yes for Digoxin, because that's what they told their customers, and that's usually the feedback we first get is when they talk to their customers about a product, they did indicate and confirm they were going to launch in October. I know October has come and gone, but unless they've launched and I didn't hear about it, they could be late by a week. But, yes, I still expect it to be imminent.

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

Okay. And then so if Hikma West-Ward came out in the next quarter, let's say, or fiscal 3Q, would that force you to take down Digoxin guidance? I know you're saying that Mylan is a wash with Hikma and Sun. But if Hikma comes out -- or I'm sorry, West-Ward comes out in the next quarter or so, how does that impact your Digoxin forecast?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

I don't really think it would. Remember, we've been trying to tell you, even though we take the conservative approach and as soon we'll lose market share, the reality is West-Ward could take market share away strictly from Impax, strictly from par and not from Lannett at all. So none of our customers may leave us and we'll continue to do the volume we're talking about. But when we make our guidances, or we give out guidances or talk internally, we assume worst-case scenario. But since the companies we're looking at here are not irrational players, I don't see them just going out and trying to grab market share. They'll solicit customers when they're ready to ship and they'll start to make some inroads in a small way, so it still won't impact us. If they haven't launched yet, we're already into our second quarter. So what are we talking about? Maybe the third and fourth quarter, they might start to pick up some business. And remember, their customers carry inventories. They're not sitting there with an empty shelf waiting for vendors, so they may not be ready to buy for a quarter at least. So that gives me at least 3 quarters of some comfort.

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

And our second half outlook is -- our numbers that are in the guidance are pretty -- are conservative yet on Digoxin.

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

Okay. And then with the approval on Letrozole, I think you mentioned that you have 21 ANDAs pending at the FDA. This one took 4 years. What is the average -- I guess, for the other 21 products, what is kind of the average length of stay for those products?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Well, it's hard to say because we've got 1 approved in 14 months recently, which we weren't expecting. We thought it was a mistake as it came real quick. But generally, they're running up certainly closer to 4 and 5 years...

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

I don't mean what's the average FDA time line. I meant your specific products, the 21 products, what is the average time line that you have there, sitting there? Does that makes sense?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Oh, I'm going to say for probably half of that, say at least 10 of those products have been down there close to 4 years.

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

Okay. And then the China partnership, where do we stand on that?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Well, they're expecting some approvals -- they're expecting 2 approvals by December that we'll be distributing of theirs. They have pretty large-volume products. But we don't have any indication other than their feelings, and we all know none of us can predict the FDA. They are continuing to work on the contract manufacturing proposal that they have made, so we're waiting for some quotes on some products that we've asked them to consider making for us. And they really haven't done much on the API side. So this thing is starting off a little bit slow. But remember, it was a multipart agreement and I do think that it was, I would say, almost the first foray for them into the United States. So I'm expecting a little more responses, I'd say, in the next month or 2 from them with regards to the other 2 product lines, which would be the API support, the dosage forms that they want to quote on, which we've given them already, and now, of course, the 2 products that are at the agency. We hope that they're right about when they'll be approved. But I'll know a little bit more as we've had more contacts. We're also been authorized by them to contact the agency on their behalf. So with my staff following up, I'll have a little more information in the next few weeks.

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

Okay. And then the last question from me is on the AG investigation. You submitted everything to him, and then did he give a time line? Or what are the next steps? You just have to wait for him to go through all the data?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Exactly, I'll wait for him to go through all the data.

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

And there's no time line on how long that could take him?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

No. We're inexperienced in this area, though, you're not going to even get a guess out of me. Governments are so slow, I don't know what to tell you.

Operator

I see nobody else in the queue. I will now turn the call back over to management for closing remarks.

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Thank you, Vivian, and thank you again for joining us today. We're always available to answer further questions and look forward to reporting on our continued progress on our next call. Thank you.

Operator
Thank you, ladies and gentlemen, this concludes today's conference. Thank you for participating. You may now disconnect.

EXHIBIT “5”

February 4, 2015 Lannett Earnings Call

S&P CAPITAL IQ
McGRAW HILL FINANCIAL

CONTENTS

Lannett Company, Inc. NYSE:LCI

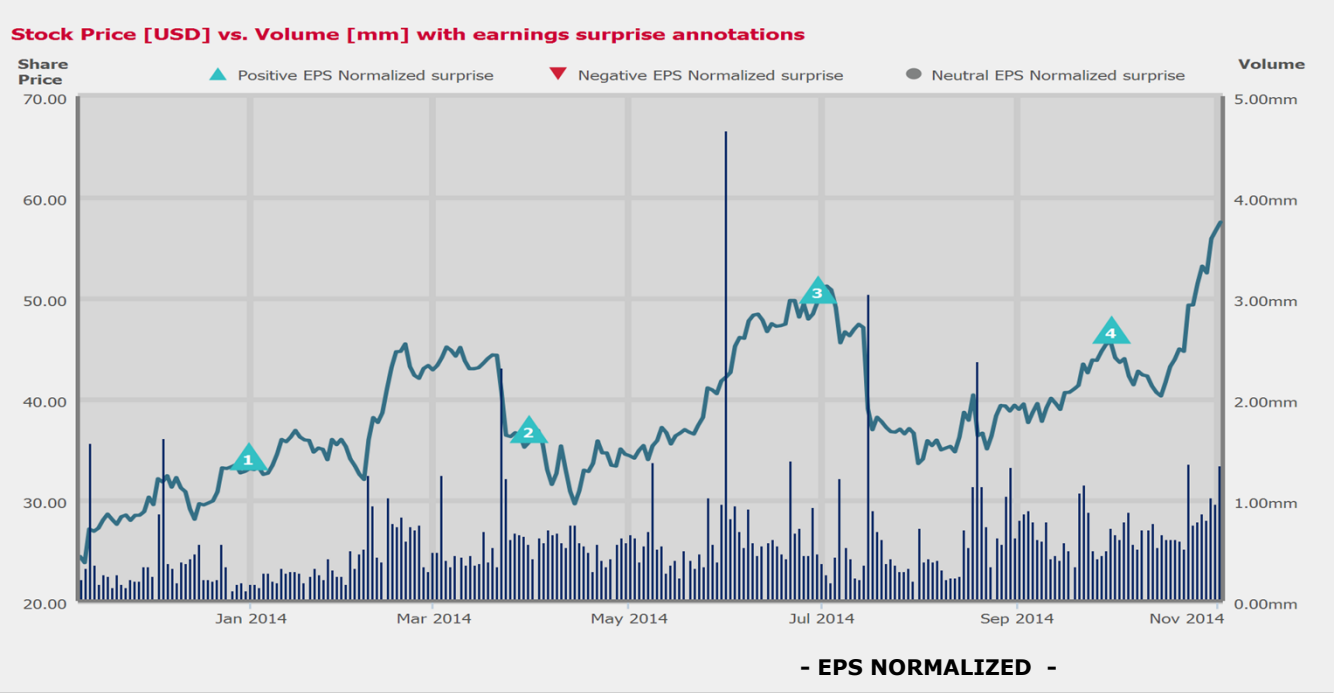
FQ2 2015 Earnings Call Transcripts

Wednesday, February 04, 2015 9:30 PM GMT

S&P Capital IQ Estimates

	-FQ2 2015-			-FQ3 2015-	-FY 2015-	-FY 2016-
	CONSENSUS	ACTUAL	SURPRISE	CONSENSUS	CONSENSUS	CONSENSUS
EPS Normalized	1.10	1.21	▲10.00	0.92	3.86	3.75
Revenue (mm)	115.09	114.82	▼(0.23 %)	101.97	403.06	445.80

Currency: USD
Consensus as of Feb-02-2015 9:30 PM GMT



- EPS NORMALIZED -

	CONSENSUS	ACTUAL	SURPRISE
FQ2 2014	0.35	0.46	▲1 31.43 %
FQ3 2014	0.61	0.63	▲2 3.28 %
FQ4 2014	0.62	0.64	▲3 3.23 %
FQ1 2015	0.81	0.94	▲4 16.05 %

Call Participants

EXECUTIVES

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Robert Jaffe
Principal and Senior Vice President

ANALYSTS

Elliot Henry Wilbur
Needham & Company, LLC, Research Division

Gregory B. Gilbert
Deutsche Bank AG, Research Division

John L. Newman
Canaccord Genuity, Research Division

Matthew Gregory Hewitt
Craig-Hallum Capital Group LLC, Research Division

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

Sumant S. Kulkarni
BofA Merrill Lynch, Research Division

Presentation

Operator

Welcome to the Lannett Company Fiscal 2015 Second Quarter Financial Results Conference Call. My name is Adrian, and I'll be your operator for today's call. [Operator Instructions] Please note that this conference is being recorded. I'll now turn the call over to Robert Jaffe. Robert Jaffe, you may begin.

Robert Jaffe
Principal and Senior Vice President

Thanks, operator. Good afternoon, everyone, and thank you for joining us today to discuss Lannett Company's Fiscal 2015 Second Quarter Financial Results. On the call today are Arthur Bedrosian, Chief Executive Officer; and Marty Galvan, Chief Financial Officer. This call is being broadcast live at www.lannett.com. A playback will be available for 3 months on Lannett's website.

I would like to make the cautionary statement and remind everyone that all of the information discussed on today's call is covered under the Safe Harbor provisions of the Litigation Reform Act.

The company's discussion will include forward-looking information reflecting management's current forecast of certain aspects of the company's future, and actual results could differ materially from those stated or implied.

This afternoon, Arthur will provide a brief overview, and Marty will discuss the financial results of the quarter in more detail, followed by Arthur's concluding remarks. We'll then open the call for questions. With that said, I'll now turn the call over to Arthur Bedrosian. Arthur?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Thanks, Robert, and good afternoon, everyone. I hope you enjoyed our latest theme song, Don't Stop by Fleetwood Mac. Before I begin, let me welcome Michael Bogda as Lannett's President. Michael brings a global perspective, extensive operations, merger and acquisitions and business integration experience. He joined us in December after having held senior level positions with some respected companies in our industry. The addition of Michael will strengthen our team, help us manage our recent rapid growth and bolster our M&A program.

Turning to our financial results. We had a tremendous quarter driven by strong sales across multiple product categories and a significant increase in gross margin. For fiscal 2015 second quarter, we recorded the highest net sales and net income in our company's history. Net sales were $115 million with gross margin of 76% and net income was $45 million, equal to $1.21 per diluted share. We have now reported 9 consecutive quarters of record net sales as well as the 12th consecutive quarter in which net sales and adjusted earnings per share exceeded the comparable prior year period.

Our outlook for fiscal 2015 remains strong. And with the excellent performance in the second quarter, we have raised our full year guidance. Marty will discuss in more detail shortly. With that brief overview, I'd like to turn the call over to Marty to review the financials, then I will provide an update and we'll open the call for questions. Marty?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Thank you, Arthur, and good afternoon, everyone. As Arthur mentioned, we reported an outstanding fiscal 2015 second quarter with net sales increasing 71%, $114.8 million from $67.3 million in last year's second quarter. Net sales for our largest product category, thyroid deficiency, moved to $44.5 million or 39% of our total sales. 2 of the largest categories, cardiovascular and gallstone, had net sales of $18.3 million and $16.7 million, respectively, representing 16% and 15% of our total net sales, respectively.

As for the net sales of our remaining categories, pain management was $7.6 million; migraine was $6.9 million; glaucoma was $5.5 million; antibiotic was $3.3 million; gout was $3.0 million; obesity was $953,000; and other represented $7.9 million.

Gross profit more than doubled at $87.2 million or 76% of net sales from $41.0 million or 61% of net sales. Research and development expenses increased to $7.8 million compared with $5.8 million in the same quarter of the prior year. Selling, general and administrative expenses increased to $12.8 million compared with $9.9 million. This amount includes acquisition-related expenses of $2.0 million or approximately $0.04 per diluted share.

Operating income more than doubled to $66.5 million from $25.4 million in the second quarter of last year. The effective tax rate was 33% compared to 37% for last year's second quarter. The lower effective tax rate was due primarily to changes in the Philadelphia local tax laws, as well as higher federal domestic manufacturing deductions recorded in fiscal 2015 and related to a shift in our product mix. In addition, Congress recently extended the R&D tax credit law, which also contributed to a lower rate. Net income attributable to Lannett Company grew by 170% to $44.8 million or $1.21 per diluted share from $16.6 million or $0.46 per diluted share for the second quarter of fiscal 2014.

Turning to our results for the first 6 months of fiscal 2015. Net sales increased 84% to $208.2 million from $113.2 million for the first 6 months of last year. Continuing with the remainder of the income statement and for completeness and comparative purposes, I'll provide both GAAP and adjusted amounts for last year's second quarter results. As you may recall, in last year's first quarter, we issued 1.5 million shares of our common stock in connection with the signing of a contract extension with Jerome Stevens Pharmaceuticals. Accordingly, cost of sales included a nonrecurring pretax charge of $20.1 million related to this contract extension.

Gross profit was $158.8 million or 76% of net sales. This compares with gross profit last year of $42.3 million or 37% of net sales. Gross profit, excluding the JSP contract renewal charge, was $62.4 million or 55% of net sales. Research and development expenses increased to $14.2 million compared with $10.5 million in the same period of the prior year. Selling, general and administrative expenses increased to $23.4 million compared with $17.1 million. This increase includes the acquisition-related expenses of $2.1 million or approximately $0.04 per diluted share.

Operating income was $121.2 million compared with $14.7 million. Excluding the JSP contract renewal charge, operating income was $34.8 million in the first 6 months of last year. Net income attributable to Lannett Company was $79.7 million or $2.15 per diluted share compared with $10.6 million or $0.31 per diluted share. Adjusted net income, which excludes the contract renewal charge, was $23.2 million or $0.69 per diluted share for the first 6 months of fiscal 2014. Our balance sheet at December 31, 2014, remained strong with cash, cash equivalents and investment securities totaling $184.9 million.

Turning now to our guidance. Given our strong second quarter performance, we're ready for guidance for the full year 2015 as follows: Net sales in the range of $395 million to $405 million, up from previous guidance of $370 million and $390 million; gross margin as a percentage of net sales of approximately 74% to 75%, revised from 73% to 75%; R&D expense in the range of $29 million to $31 million, down from previous guidance of $34 million to $36 million; SG&A expense ranging from $47 million to $49 million, up from $46 million to $48 million; the full year effective tax rate to be in the range of 34% to 35%, down from previous guidance of 36% to 38%; capital expenditures in fiscal 2015 in the range of $40 million to $50 million, which includes $7 million to continue the partial fit-out of 2 buildings recently acquired by the company, and this is unchanged from previous guidance. Regarding the phasing of the third and fourth quarters in fiscal 2015, we expect the results of Q3 and Q4 to be similar to each other. With that, I will now turn the call back over to Arthur.

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Thank you, Marty. For the quarter, we recorded strong sales across a number of product categories, including cardiovascular, gallstone, glaucoma, migraine and thyroid deficiency. As expected, Digoxin sales

declined modestly compared with sales in the first quarter due to competition. The guidance Marty just provided anticipates further reductions in the second half of fiscal 2015.

We also saw increased sales of our C-Topical product. We believe our company is well positioned for continued growth and success. The alliances we have formed are in various stages of development or marketing and on the business development and M&A fronts, we have undertaken 2 due diligence evaluations of potential acquisitions and continue to seek out acquisition opportunities for both products and companies. [indiscernible] the M&A pipeline of companies that are in some stage of negotiations. And while I cannot project when or if the transaction will close, I remain optimistic. Our team continues to look at opportunities that are a strategic fit and accretive to our business. We are particularly interested in opportunities that globalize our business further vertically integrating our operations or enhance shareholder value through an acquisition in a tax favorable jurisdiction.

In late December, we announced the approval of Dorzolamide Hydrochloride with Timolol. This is the fourth FDA approval we have received thus far in fiscal 2015. While total sales of the product are significant, we have a late entry in the market, and therefore have modest expectations for the product.

We continue to increase our pipeline. We currently have 20 ANDAs, including 5 with Pfizer for certification pending an FDA.

As expected, Selegiline stood against this regarding our thalidomide generic, one of our power growth core products, and we are pleased the FDA has initiated their review of the application. Of our additional 42 products in various stages of development, we expect to submit several additional product applications in the near future. And our plans call for continued significant investments in R&D.

With regard to our C-Topical solution product, we had targeted December 2014 to submit our new drug application. However, due to minor delays in the recruitment of patients as well as minor issues with the clinical trial, a meeting was requested with the FDA. That meeting was held recently and we are in agreement with FDA on the recommended changes to the protocol. We are revising the filing date of our NDA to late calendar 2015. We have been invited and expect to present in a number of investor conferences over the next several months.
I want to thank our entire staff for doing an outstanding job and to our shareholders and board members who have continued to support our efforts. We remain very positive about Lannett's future. Marty and I would now like to address any questions you may have. Operator, Adrian?

Question and Answer

Operator

[Operator Instructions] And we have Matt Hewitt from Craig-Hallum Capital.

Matthew Gregory Hewitt
Craig-Hallum Capital Group LLC, Research Division

First question, the source of the upside in Q2. It looks like both Levo and gallstone were up. Gallstone, you took price up last quarter, is that correct? And Levo, was that just volume gains?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Well, Matt, in both cases, as far as the very strong quarter that was a bit beyond our own expectations. It was volume in both cases.

Matthew Gregory Hewitt
Craig-Hallum Capital Group LLC, Research Division

Okay. And I get ...

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

There was some price on the gall product, but -- I mean, the driver that gave us a great quarter was volume.

Matthew Gregory Hewitt
Craig-Hallum Capital Group LLC, Research Division

Okay. A question I get a lot, I'm sure you guys are getting a lot as well is with Levo, the potential or expectation for generic entrants. And I'm wondering and I think this will be helpful for everybody, but as far as that drug is concerned, it's not a simple generic or another competitor enters the market and the doctors can switch over. Could you maybe remind everybody how that drug is differentiated as far as patient -- the patients are concerned?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Yes, so it's a Narrow Therapeutic Index Drug and there's 13 different strains and while the generic companies are generally comparable to each other or bioequivalent to each other, you still have the concern that between the label claim of 95% to 105%, you can have one generic drug making, let's say, a 25 micrograms strength at 95%, 96% level. And then another generic company making closer to 104%. So there's a significant difference between those 2 strengths and this is a very sensitive product. So not every patient could be easily switched from one product to another. And if you look in the Orange Book, you'll find the FDA has 4 different AB rating categories for this drug. So a lot of physicians don't want to change patients once they are acclimated to the particular generic they're using or even to the brand. And that explains why the brand, and I'm talking about the Synthroid product in particular, has continued to maintain a major market share for themselves on a product that's been available generically for well over 15 years. And that would really be the major stumbling block for any new generic that comes into the marketplace. Grabbing market share away from another company would mean possibly having patients not respond as well to the medication and some physicians don't like dealing with that. Everybody's doing fine with their medication, why change it and create problems? So I believe, as a result, this is one of those drugs where you are not going to seeing any dramatic market changes in the marketplace itself. I hope that answers your question.

Matthew Gregory Hewitt

Craig-Hallum Capital Group LLC, Research Division

Yes, absolutely. That was perfect. Maybe one quick one for me. R&D spend looks like it's going to decline. Is that a function of the NDA being pushed out a little bit for C-Topical?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Well, that's part of it, Matt. The -- our expectations are that the expense in the third quarter -- the fiscal third quarter will be on the low side relative to -- and as Arthur explained in his prepared comments. And then also the expense at the stage for the fourth quarter would ramp up as compared to the third. But, yes, in total then it is down versus what we were projecting.

Operator

And our next question comes from John Newman from Canaccord.

John L. Newman
Canaccord Genuity, Research Division

The question I have is, should we expect to see the same pattern of price increases over the course of the year in the various therapeutic areas that we've seen over the past 12 months? And the second question I have is, Marty, have there been any changes to the level of reserves that you have been taking on the products when you take price increases or has that been relatively constant?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Let me take the first part of your question just so we're clear. If you're saying that the price increases that we've had in place, are they sustainable? And are they maintaining? My answer would be, yes. They continue to hold up. As far as whether we talked about any increases for this year, we don't usually give you guidance for that. We predict what our revenues will be for the year. We're not seeing any declines, generally speaking, on the price increased products. So they continue to, let's say, level off at their new pricing. So from that point of view, there's no planned increases, per say, in each one of the products that we've previously increased, while on occasion, some products have gone through a second round of increases. And I think Marty can address the issue about the reserves.

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

On reserves, John, I would just say that commensurate with our sales increase, you'll generally see our reserves expanding or growing consistent with the top line growth.

John L. Newman
Canaccord Genuity, Research Division

Okay. But in terms of the percentage of revenues, would you say that the reserve level is remaining relatively constant?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

It is consistent, yes.

Operator

And our next question comes from Elliot Wilbur from Needham & Company.

Elliot Henry Wilbur
Needham & Company, LLC, Research Division

A couple of product-specific questions. First, ongoing back to Levothyroxine and the strength in the quarter, is there anything that you could perhaps share with us in terms of maybe provide a little bit more clarity on what exactly drove that? Certainly, looking at various services that provide prescription data, I mean that product has been very, very constant in terms of end market demand. So a little bit surprising to see kind of such a significant step up in one particular quarter. Even assuming it was a new customer win, it would seem like at this point it would be reflected in RxData, so I'm just trying to get a little bit better sense as to what exactly drove that in the quarter. So based on your guidance, it doesn't seem like you're expecting that to continue through the back half of the year. And then, Art, I want to ask you questions specifically around Digoxin. You talked about this product in terms of potentially having additional pricing leverage and sort of giving still significant discount versus the brand. And given the possibility of additional competitive entrants, sometime in the not-so-distant future, it would seem like this would be a very advantageous time in which to move forward with a more aggressive pricing strategy rather than waiting for potentially other players to come back into the marketplace. So I just want to get your thoughts on sort of the outlook for the competitive environment around Digoxin and then some commentary maybe on the potential relative pricing dynamics in the market.

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Let me take the Levo first. I would say that probably the growth you're seeing in the Levo where you're not noticing it in the IMS data because the IMS data is essentially tracking the percentage of the marketplace that we have. So I believe maybe our percentages might have stayed the same even though we're capturing more share of the brand market and probably getting some sales in areas that are not reported through IMS, because we certainly have seen unit increases in those product sales and we continue to see that. We've also known we've taken a lot of market share from the Levoxyl product. When they left the marketplace, it was one of those scenarios where one of their biggest customers switched the product to us on 2 stages. First, when Levoxyl raised their price on the product, we picked up the generic market that they were occupying with their generic pricing. When Levoxyl left the market completely and the brand portion of that market was also brought under our control by that customer. So we were picking up some unusual business from Levoxyl as supposed to our competitors, let's say, in the market place, and that might account for some of it. The other part I'd have to say it's just the learning [ph] away at the Synthroid market. But we have seen an increase in the unit sales ourselves. It's a product that -- a lot of people like our product for a lot of reasons. One of which is never having a recall on it and this product's been on the market over 30 years. It is one of the best -- it is the best formula, I'll say, in the market place in terms of that history. So it may just be that the loyalty that the physicians and the patients show to this product is coming through in increased unit sales. That would be my best guess because the IMS data is not that reliable and not that accurate in terms of what's going on today because it reflects what's happening on a historical basis. So I may know a little more as you will as we see the IMS data change going forward. And it may reflect what I'm thinking that it we're taking more market share away from the Synthroid products. Getting back to the Digoxin, yes, there was some interest on my part in raising the price of the Digoxin before we had the entrance of Mylan and West-Ward into the marketplace. The problem with that though is sometimes the timing isn't right, but I'm still concerned about the pricing potential, meaning the prices could go higher because there's an issue now with the raw material. Most people in the market place are using raw material by one supplier. That supplier has decided to discontinue the product. They're planning on selling their Drug Master File to another firm. So there's a potential for disruption in the marketplace if everybody doesn't have enough raw material available. And that disruption certainly could equate to a price increase for us. So, well, I'd just say stay tuned. But we're also looking to capture more market share on the Digoxin. Now this is an important product for us. We don't want to sit by and just let our competition take away our market share.

Elliot Henry Wilbur
Needham & Company, LLC, Research Division

And Art, if I could follow up your earlier comments on Levothyroxine with additional questions. I mean, given the fact that it seems like you're suggesting that the bump up seems to be sustainable and ultimately something that we'll be able to figure out why or see it more accurately reflected in the IMS data. I guess, again, sort of thinking about back half of the year in terms of top line guidance, why --

doesn't seem like we would -- or should be thinking about any sort of meaningful step down from the current run rate. So I'm just trying to get a sense of conservatism embedded in second half versus knowing something specifically about Levo or in one of the other major products.

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Yes, so Elliot, this is Marty. So in our guidance that we provided, we have taken the Levo full year number up. Previously, we were talking about a number of $150 million. Now, our number is $155 million, essentially reflecting the upside that you saw in the second quarter. So in our numbers, we are still expecting Levo sales to drop down and be fairly similar in the third and fourth quarters. And some of that is -- and some of what we do know in terms of agreements with our customers, and some of it -- there's a bit of conservatism in there perhaps, but we're keeping the second half. The way the numbers fall out actually is that the second half is only slightly lower than the first half. Our first quarter -- if you look at the first quarter, it might have been a bit lower than we were expecting and then we spiked in the second quarter. So our thinking is somewhat predominantly thinking that it's maybe one half versus the second half exercise. And with the current guidance at $155 million, we essentially have the first half -- the second half that is equal to the first half. And, again, we do know some pieces of the business that would cause the second or cause the third and fourth quarters to be down a bit versus the second.

Elliot Henry Wilbur
Needham & Company, LLC, Research Division

Okay. And if I could ask one last question of -- Art, in terms of current thinking around M&A possibilities. Obviously, we've talked in the past about this being a seller's market. And no secrets, you've had kind of a short list for some time on some potential transactions. Just kind of wondering how would you -- what would you characterize sort of the biggest impediment or the biggest stumbling block in terms of moving forward the transaction? Is it simply price? Or you just haven't yet found the right deal?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

I have to say that it's probably the narrow focus that we placed upon ourselves. We promised The Street that we would stay within the area that we operate in and that we'd make sure that they were accretive. So there were a lot of opportunities that were out there that would not be accretive for us. And we didn't want to go back on our word. Everybody's expecting us to keep within that framework. So it means I can't go into -- for example, I wouldn't be buying a brand product because I said I'm going to stay in the generic field. I think that limits my opportunities. And we're certainly looking at whether or not we should change that but if I'm going to change it, I'm going to change it after I tell the shareholders of my intentions, not before. But right now, that's really been the impediment. You narrow the focus so you don't have all of those opportunities that are out there available to you. All the companies, for example, that have been thrown at us from Ireland because of potential inversions or even the Canadian company, were not companies that fit in that criteria of being accretive and being in the same space that we're in. So because it's going to be our first acquisition, we wanted to make sure that we handled something that everybody on The Street would understand we were capable of integrating and merging with and handling successfully as opposed to taking some risks. We'll take risks once we have a little more experience under our belt.

Operator

And your next question comes from Greg Gilbert from Deutsche Bank.

Gregory B. Gilbert
Deutsche Bank AG, Research Division

Maybe just a follow-up on that last question, Arthur. I'm intrigued about your comments about globalizing the business aside from tax inversion kind of things. What are the things that you're considering or thinking about as they relate to globalness? Where would you go? Where would you not go, et cetera?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

I wouldn't go to Afghanistan, that's for sure. Other than a place like that we are really open to anything, I would say, within Western Europe -- is where we're focused. But actually, the globalization we're talking about happens to be a company that's very attractive to us, that's also a good candidate for inversion. So it just happened to be also a candidate for inversion. It wasn't that we started just looking for an inversion candidate. Again, we'll look into something that fits that narrow criteria we put in front of ourselves. We did look at companies in Europe and we did spend some money on our due diligence. And at this point, we did view the potential for the globalization of our company if we made any one of those 2 potential acquisitions. But at this point, I can't say any more other than that. But we are looking in the marketplace and we have looked at Europe. But that was not the main focus. We came across companies that were very attractive in that market, but not because we were looking for European companies. I hope that answers the question.

Gregory B. Gilbert
Deutsche Bank AG, Research Division

Yes. And my other question is a bit more of an industry question, you've been in the industry a long time, not to date you, Arthur, but I'm curious about your thoughts on sort of the sustainability of pricing not on each of your products as already asked and answered but rather what are some of the themes and trends you're looking at to assess whether this pretty good environment is going to continue?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Okay, I'll start by saying you're as young as you feel and I still feel young, so I'm going to forget about my age, at least I try to every day. Seriously though, with regards to the market, we've sustained these price increases now probably close to 3 years. So it's kind of hard, not all of them, but over time, depending on when you look at the first one. It's my understanding that the entire generic marketplace has probably looked at the cost structure of our ANDA going forward and have realized that to be in a competitive marketplace may mean if we sell on price we won't be in business in the future. The cost to follow an ANDA, in my estimation, is probably quadrupled and I'm putting together some statistics to prove that because there's been a lot of changes in the marketplace. I mean, if you just look at the latest budget from Obama, he's increasing use of these. So what we're having is, every time you turn around, the cost of file an ANDA, the cost to do business with the FDA is going up and up and up. The PDUFA fees for your convertible products -- the products that are grandfathered, converting to license products, the PDUFA fees are close to $3 million now. When we did our marketing [indiscernible], it was only $1 million. So all of the fees, all the expenses go up and up and up. And we look at these price increases as being sustainable because everybody is faced with those same costs. The PDUFA fees, as we now know, are not going to go down. So we're not getting the benefit we expected from it, but we're certainly getting increases in the fees. So I'm expecting these prices to really sustain themselves, to continue. I see people raising prices further because the generic prices were so low, only 10% of the brand. That's not because the brand overpriced the product 90%. It's because the generic marketplace has so much competition sometimes people get desperate just to unload their inventory that they cut the prices. We don't see that kind of behavior as sustainable and we don't see it going forward into the future. I think you're going to find more careful pricing. Obviously, less competition in the sense you won't have price wars. You're still going to have competition because there's a lot of generic companies in the market. You just don't see the prices eroding like they did in the past. It's really unfortunate, but with they see is significant pricing -- cost increase, I should say, that are driving this.

Operator

And our next question comes with Scott Henry from Roth Capital.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

I guess, just getting started, 2015, your fiscal year 2015 has been a tremendous year, a lot of pricing influences. My question is, at this point in time, how are you starting to think about 2016, if just directionally? I know you're going to hit some headwinds possibly on Digoxin, maybe at some point in Levo. I mean should we think about '16 as being a flat year? Should we think about it up or down? Just obviously, big picture.

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Well, I guess the best way I can answer that is it's probably too early to provide a guidance for 2016 at this time. But I can offer my thoughts regarding our outlook for sales next year. I think our sales will increase next year and I expect the increase to be the second half of the fiscal year and primarily due to new product approvals. Will existing products also increase? Or will they decrease due to increased competition? I expect a modest volume increase in sales of our existing products as compared to the second half of fiscal 2015. And my thoughts with regards to price increases and decreases, I think I've just really touched on that. There are no forecasted price increases in our estimates for next year. In addition, any anticipated price decreases are already in our guidance for this fiscal year. So I really struggle to say that the year would be flat. We are looking at some growth in that year. We certainly can't predict whether there'll be any price increases that will add to the growth. But we're certainly looking at unit growth in sales of the products that we manufacture, bringing products to the market, returning them to the market are opportunities for us that we are looking at presently. And I'm always an optimistic, of course, but I see 2016 as a growth year.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

Okay. That is helpful. Shifting to Digoxin, you made comments about a raw material supplier possibly having some disruption. Could you just confirm, one, if you also use that same raw material supplier? And then, perhaps, if you could talk about what kind of inventory you have on hand.

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Well, we are in a good position on inventory. But, yes, I believe everybody in the marketplace in Digoxin is using that same vendor at this time. I believe there was essentially just one vendor. There have been a couple of new entrants into the market that have talked about getting involved in Digoxin. But I believe from the Drug Master Files that are available to us, I believe we're all using the same supplier. So that's what concerns me. If they're switching to another source and that person makes any changes to the formulation, the process, the manufacturing, what have you, there could be some disruptions. I can't speak for everyone in the industry, but they're all aware of this problem. So I'm assuming everyone is, of course, taking steps to make sure they don't run out of inventory. But if they do or they don't, I certainly think people are going to be a little cautious about trying to grab market share in that scenario, because if you go out and you grab the market share and then you're unable to supply because you're unable to get raw material, then you're going to be hit with those failure to supply. So I see a real steadiness to the market and probably some growth if some of our competitors are unable to supply all the needs of their customers. So I just don't see this as a very competitive market because of that problem.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

Okay. And you mentioned you had a good inventory position. Should we think about that being 6 months? Or I don't know how much color you want to provide. And as well, with a new supplier, do you have any -- I guess, do you have any -- is the pricing fixed? Or at some point, is the supplier going to raise price? How should we think about that?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Well, I would always assume the supplier is going to raise price, especially if he has purchased a drug that he has to file and he's going to start launching it. I would presume that. I can't really speak to the inventory on raw materials because I don't know the answer to that at the moment. But we certainly at least try to make sure that we have good service levels so I'm always presuming that our partner at Jerome Stevens will always make sure that they are in a good position on raw material. But nevertheless I would presume there's some raw material increases in our future, just from the norm, that's the way companies behave. But I can't speak to any particular contracts that have been transferred, for example, so there may be some opportunities where we have to be given notice before they can change the price. I'm not in the raw material purchasing side, so I really can't add much color to that. I may have come back to you with an answer once I look into that question.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

Okay, fair enough. Shifting gears, with regards to Levothyroxine, there was that approval for Lloyd, which I guess is ultimately Actavis for Levothroid. Anything new on that front? Do you expect that to be another brand? Or might it come out as a generic? Or I guess, relaunched as a generic? It would seem likely it would be a brand.

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Originally, it was a brand. Lloyd's made that product for Forest. So we were presuming that and they are stating that they're going to relaunch Levothroid. So it sounds to me that they're coming into the market as a branded generic at the very least, because there's already 2 brands out there in multiple generics. So I'm presuming that they're launching. That is our opinion. I have heard from one company who claims that Actavis was planning on making sure that product was equivalent to all the other generics out there. But that doesn't necessarily mean that their plan is to sell it is a generic. They may be doing that so they can make sure all the patients could be switched to their brand, away from Synthroid or our Levo our competitors' generic Levos that are out there. But right now, we're not expecting anything dramatic to happen with that product. As you know, the company had some severe FDA issues with their formula. They believed they've gotten them resolved. We'll see how well that goes in the marketplace. If they launch and have recalls then they will lose market share rather quickly. So I'm really going to take a wait and see. But, again, this is a product that the patients don't like to be switched, the doctors don't want to switch. The customers that we have don't want to go through that process either. So I don't really see any unit loss to us, and we hope to continue to keep our market share on that product. I just -- look, no one likes additional competition, especially me, but I'm not concerned about this particular product hurting us that much.

Operator

And your next question comes from Rohit Vanjani from Oppenheimer.

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

On the R&D and tax rate guidance. So the tax rate guidance you were able to take down, Marty, because of some of those issues you talked about, the Philadelphia issues and the R&D tax credit. Is that why the whole year came down, because of the quarter?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

correct. That's right.

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

And then I was a little bit confused on the R&D guidance. You said that the filing got pushed for C-Topical to the end of calendar 2015. But was there something else that caused you to lower the R&D guidance?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Well, some of the, as Arthur mentioned in discussions with the FDA about the protocol, we actually had some of the testing, the Phase III testing was on hold while we were talking to the FDA. So that's causing the expense that we are incurring, like right now, to be lower than what we were expecting, say, 3 months ago. So that's why we brought down the full year outlook for fiscal 2015.

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

Okay. And then, Arthur, some of those products that we talked about a couple quarter ago slipping from fiscal 2014, the CIMB product, the cytotoxic drug product. Have you heard anything from the FDA on those products?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

No, the only one that we've kind of heard about really is the THALOMID because we know that they have started to review that application already. So that's good in a way. Of course, there's litigation with Celgene, so clearly, there's a 30 month hold that comes with that litigation. So not to expect anything tomorrow. But, no, still don't have any idea or any clues when the FDA is going to approve anything over the next few months.

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

Okay. And then on the components of guidance. I think you said Levo is $155 million in fiscal 2015, right? And so you're expecting -- and then you've talked about now up -- out to fiscal 2019. So you have flattish sales for Levo out to the fiscal 2018 before dropping into fiscal 2019, is that right?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

That's about right, yes.

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

Okay. And then for fiscal 2015, you have Digoxin still at $45 million?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Digoxin, we've taken it up to $50 million. Again, we sort of like with Levo we rolled into the whole year outlook the upside that we saw in the second quarter.

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

Okay. And then Ursodiol was at $35 million. You took that up as well?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Ursodiol, last time we talked about it $50 million actually, and we've taken it up again now just based on what we can see for the rest of the fiscal year. So we've taken that up to $60 million for the fiscal year.

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

So Ursodiol, I thought was at $50 million and then you dropped it to $25 million and then you brought it back up, no? It was always at $50 million and now you brought it up to $60 million?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

On Ursodiol, no. We started like 3 quarters or 4 quarters ago at $25 million first. It was a $5 million product. We increased it up to $50 million in terms of our outlook. So back in the May call, we started with $25 million for fiscal 2015. We took it up to $35 million next time around. And we just increased it to $50 million last time. And now it's at $60 million. It's getting confident. As you recall last summer, we felt that with the significant price increase, it just wasn't quite clear -- with Epic, was the other competitor at that time and the outlook wasn't clear. So we only put 6 months of that price increase into our fiscal 2015 outlook. Now, essentially, we have 12 months of that price increase plus some volume increase.

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

Okay. And then C-Topical, I think last quarter, you had it at $25 million to $30 million. Where is that now?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Same. We've held that as it is, the same place in the current guidance, Rohit.

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

And then, is there dorzolamide product in your guidance?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

No.

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

That is not?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

No.

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

Okay. And there was no other product approvals or anticipated approvals in there?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

I'm always there anticipating approvals, but they're not in our guidance until we get them.

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

Okay. And then the last question for me is, I think last quarter we saw a entrant in the Digoxin market. I think you mentioned it, Mylan. I don't think that competitor was able to take share for you in the reported quarter, but are you seeing them taking share from you in this current quarter, fiscal 3Q?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

You got to be careful, those 2 entrants now, Mylan and West-Ward. So we've seen some market share lost to some of them, but not necessarily the first one that introduced. So it's not necessarily Mylan, it might be West-Ward or a combination of them. So I didn't lose anything to Mylan, I lost some to West-Ward is the way I'll answer that.

Operator

And your next question comes from Sumant Kulkarni from Bank of America.

Sumant S. Kulkarni
BofA Merrill Lynch, Research Division

Arthur, could you give us an update on the latest on your Dronabinol filing?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Not really. It's still with the agency and not much I can tell you. I've given up on predicting anything with the agency. I've been wrong on this one too many times. So I'm just going to wait until it gets approved.

Sumant S. Kulkarni
BofA Merrill Lynch, Research Division

And then how has the progress been vertical integration on the controlled substance part of the business because that's something we've not been focused on given the positive dynamics in the other parts of the business?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Well, the vertical integration is not as pronounced as you might expect because our subsidiary, that's the riskiest side of our business. So we always want to make sure that, that operates as a separate entity and not have its control by Lannett. It has its own board. It has its own offices and what have you. The integration, I would call it more a sharing of resources. I'm trying to think of the word we use -- shared services, one of my colleagues just reminded me. We're working on shared services with them and that's moving forward nicely.

Operator

And I'd now like to turn the call back to the speakers for closing comments.

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Well, thank you very much, everyone, for joining the call. I look forward to speaking to you on our next earnings call.

Operator
Thank you, ladies and gentlemen. This concludes today's conference. Thank you for participating, and you may now disconnect.